**Island Health Research Ethics and Compliance Office**

**COVID-19 Safe Research Plan for In-Person Research**

The purpose of the Safe Research Plan is to demonstrate to the Research Ethics Board (REB) that the necessary precautions and protocols are in place to protect research participants as well as the research team from unintentional transmission of COVID-19 during research.

The Safe Research Plan is not intended to replace any safety protocols required by Island Health or Island Health sites for non-research activities. Where inconsistent requirements may apply in a location, the more stringent protections must be followed.

This template is for risks of COVID-19 only. Other risks related to this research study must be detailed in Sections 6.7 and/or 8.3 of the REB application form.

1. **Study Identification**

|  |  |
| --- | --- |
| 1. Principal Investigator’s Name | Click or tap here to enter text. |
| 1. Principal Investigator’s E-mail | Click or tap here to enter text. |
| 1. HREB or CREB | Click or tap here to enter text. |
| 1. Study Title | Click or tap here to enter text. |
| 1. REB application # | Click or tap here to enter text. |

**B. Vaccination Status of Researchers**

Are **all members of the research team** fully vaccinated? The Island Health REBs require all members of the research team to be vaccinated to undertake research affiliated with Island Health.. ‘Researcher’ is broadly understood to include students, contractors, and others (refer to the overall [policy](https://www2.gov.bc.ca/gov/content/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/current-health-issues/covid-19-novel-coronavirus) from the Office of the Provincial Health Officer). If any member(s) of the research team prefer not to disclose their vaccine status, answer ‘no’ and consult with the REB by emailing [ResearchEthics@islandhealth.ca](mailto:ResearchEthics@islandhealth.ca).

☐ Yes ☐ No

Please describe how you will confirm the vaccine status of all research team members (vaccine passport, verbal assurance, etc.).   
  
 Click or tap here to enter text.

**C. Population Risk Profile**

Describe the risk profile of the research participant group/s in relation to the COVID-19 pandemic.

*Other risks and their mitigation should be described in Boxes 6.7 and/or 8.3 of the ethics application and do not need to be repeated here*.

1. Is the age of participants a significant risk factor for this study?  
     
    ☐ Yes ☐ No
2. Are there any underlying medical conditions in the population that may increase the risk of COVID-19?  
     
    ☐ Yes ☐ No  
     
    If Yes, please explain:  
   Click or tap here to enter text.
3. Are there any other factors that might elevate the risk of exposure to COVID-19 during research activity, e.g., medical setting, high case load or outbreak area, etc.?

☐ Yes ☐ No  
  
 If Yes, please explain:  
Click or tap here to enter text.

**D. Participant Screening**

1. Will participants be pre-screened before each in-person research activity for symptoms of COVID-19, travel and/or contact with others who have COVID-19? If yes, describe who will do screening and testing. Check all that apply:
   * Symptom, travel and contact questions before arrival at the site by phone, text or website
   * Symptom, travel and contact questions when they arrive at the site, conducted by site personnel
   * Symptom, travel and contact questions when they arrive at the site, conducted by research personnel
   * Temperature check
   * Rapid antigen testing (note how frequently testing will be done, by whom)
   * Vaccination status confirmation
   * Other: describe  
     Click or tap here to enter text.
2. Describe whether these steps will be used routinely for the duration of the study, or only during outbreaks with high caseloads.   
   Click or tap here to enter text.
3. Describe the conditions that would lead you to increase or decrease screening activities.  
   Click or tap here to enter text.
4. Describe how screening information will be stored and when it will be destroyed.  
   Click or tap here to enter text.

**E.** **Research Location(s)**  
If your research will be conducted in multiple sites or geographic locations, copy and paste this section for **each distinct location**.

Location A: (provide a brief description of the location):

1. Health jurisdiction: (include the region/province/state/country that sets the public health guidelines for your research location):   
     
   Click or tap here to enter text.
2. Describe the ventilation and physical distancing options available during interactions with participants (select all that apply):

☐ Rooms are well-ventilated (windows and doors can be opened to allow fresh air to circulate; the air exchange rate is greater than 4 ACH though mechanical ventilation).

☐ Ventilation is unknown or poor  
☐ Minimal distance of 2 metres can be maintained between all researchers and participants  
☐ Minimal distance of 2 metres between all researchers and participants CANNOT be maintained or is unknown  
☐ Meetings will occur outdoors only

☐ Other  
Click or tap here to enter text.

1. Does this location has a site safety plan for COVID-19?  
    ☐ Yes ☐ No

**F. Types of interaction**

For each type of participant interaction, indicate which of the listed safety precautions will be in place (select all that apply):

* + - 1. **One-on-one**   
         ☐ N95 or KN 95 masks will be worn by researcher  
         ☐ N95 or KN 95 mask will be provided to participant  
         ☐ Other safety measures (provide explanation):

Click or tap here to enter text.

* + - 1. **Gatherings** (3 or more attendees)  
         ☐ N95 or KN 95 masks will be worn by researcher  
         ☐ N95 or KN 95 mask will be worn by and provided to participants  
         ☐ Number of participants at one time limited to \_\_\_\_\_  
         ☐ Duration of event limited to \_\_\_\_\_\_\_\_  
         ☐ Other safety measures (provide explanation):   
         Click or tap here to enter text.
      2. **Naturalistic Observation** indoors only (no interaction with people being observed)  
         ☐ N95 or KN 95 masks will be worn by researcher  
         ☐ Other safety measures (provide explanation):

Click or tap here to enter text.

**G. Community Based Research**

1. Does this research involve in-community engagement?   
   ☐ Yes ☐ No. (If no, leave the rest of this section blank.)
2. How many community groups will be involved in the research?   
   Click or tap here to enter text.
3. Who has been involved in developing the Safe Research Plan?   
   Click or tap here to enter text.
4. How many community members will the research team be in contact with?   
   Click or tap here to enter text.
5. Will the research team be required to self-isolate before beginning research?   
   ☐Yes ☐ No.

If Yes, provide details (location, duration, testing protocols):   
Click or tap here to enter text.

1. What safety protocols will be in place during research events? (select all that apply):

☐ N95 or KN 95 masks will be worn by researchers  
☐ N95 or KN 95 mask will be worn by participant/s  
☐ N95 or KN 95 mask will be provided to participant   
☐ Number of participants gathering at one time limited to \_\_\_\_\_  
☐ Duration of event/s limited to (enter max. time): \_\_\_\_\_  
☐ Other safety measures (provide explanation):  
 Click or tap here to enter text.

**H. Research Involving Indigenous Communities**

Please complete Section G above and answer the following questions. If you are unable to affirm any of the statements below, we will only be able to provide conditional approval until arrangements have been confirmed.

☐ Current letter/s of agreement have been attached to the ethics application (required before ethics approval can be granted).

☐ The community has confirmed its capacity to accept research activity at this time.

☐ The community has confirmed their guidance/policy related to COVID-19, and/or contributed to the development of this safety plan.

**I. Travel and Accommodation**

1. Will the research team need to travel to any research sites?   
   ☐ Yes ☐ No.
2. Are any travel or health advisories in effect in the location you are travelling to?   
   ☐ Yes ☐ No.
3. Will the research team be required to self-isolate before beginning research?   
   ☐ Yes ☐ No.

If Yes, provide details (location, testing protocols, etc.):   
Click or tap here to enter text.

1. Will participants need to travel to any research sites?  
    ☐ Yes ☐ No.
2. Are any travel or health advisories in effect in the location they are travelling from, and/or in the location they are travelling to?   
   ☐ Yes ☐ No.
3. Will participants be required to self-isolate before beginning research?   
   ☐ Yes ☐ No.

If Yes, provide details (location, testing protocols, etc.):   
Click or tap here to enter text.

1. Will any members of the research team come from other locations (e.g., company representative, visiting collaborator)?   
   ☐ Yes ☐ No.
2. Will some members of the local research team be travelling for other purposes not related to this research?  
    ☐ Yes ☐ No.
3. Are any travel or health advisories in effect in the location they are travelling from, and/or in the location they are travelling to?   
   ☐ Yes ☐ No.
4. Will traveling research team be required to self-isolate before beginning research?   
   ☐ Yes ☐ No.   
     
   If Yes, provide details (location, testing protocols, etc.):   
   Click or tap here to enter text.
5. Describe your communication plan to ensure that all research team members and participants are notified in the event that a surge of cases increases risk of travel.  
   Click or tap here to enter text.
6. Describe your research backup plan in the event that travel advisories or restrictions are issued.  
   Click or tap here to enter text.

**J. Exposure Response**

1. Contact tracing: Researchers must ensure that contact information for all participants and researchers is collected and stored securely (separately from research data), to be made available to Public Health authorities for contact tracing.

* Contact information for all participants will be collected and stored separately from any research data. Contact information must be held for 30 days after the last in-person contact (even if the participant leaves the study).
* Contact information for all researchers is collected and stored securely, to be used if contact tracing is needed.
* A communication plan is in place to launch contact tracing in the event that a participant, researcher or other individual in the site develops COVID-19 symptoms.

2. Have contingency plans been developed to address if a study team member or participant becomes sick or develops COVID-19 symptoms?

If Yes, please check all that apply:   
☐ Self-isolation  
☐ Rapid antigen testing  
☐ Other: Click or tap here to enter text.

If No, please explain why no contingency is needed:   
Click or tap here to enter text.

**K. Communications and Reporting**

* ☐  I confirm that Safety issues will be reported via a Request for Acknowledgement to the REB.
* ☐  I confirm that [the Island Health Notice of COVID-Related Risks During Research Version C Final 2022 Apr 22](https://www.islandhealth.ca/sites/default/files/research-ethics-compliance/documents/notice-of-covid-related-risks-during-research-vc.pdf) during research will be provided to invitees/participants before they are asked to consent.
* ☐  I confirm that research participants will be required to complete a COVID-19 Health Check before each interaction.
* ☐  I confirm that I will be responsible for maintaining the safety protocols; that changes to the Safe Research Plan will be submitted to the REB for approval and will be shared with the research team.

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| --- | --- |
| Click or tap here to enter text.   |  | | --- | |  |   Principal Investigator Signature |

Click or tap to enter a date.

|  |
| --- |
|  |

Date