Safe Research Site Plan Template: Respiratory Infection
Research Ethics and Compliance Office

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 respiratory illnesses, such as COVID-19 and influenza, 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 respiratory illnesses only. Other risks related to this research study must be detailed in Sections 6.7 and/or 8.3 of the REB application form.

Finally, this Safe Research Plan: Respiratory Infection, is only needed if the three circumstances listed in the most recent "COVID-19 and Respiratory Infections" Update.

A. Study Identification

1. Principal Investigator's Name	Click or tap here to enter text.
2. Principal Investigator's E-mail	Click or tap here to enter text.
3. HREB or CREB	Click or tap here to enter text.
4. Study Title	Click or tap here to enter text.
5. REB application #	Click or tap here to enter text.

B. Population Risk Profile

Describe the risk profile of the research participant group(s) in relation to COVID-19, influenza, and other respiratory infections.

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 likelihood and/or severity of respiratory infections?

   ☐ 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 or severity of respiratory infections during research activity, e.g., medical setting, high case load or outbreak area, immune suppression related to the research intervention, etc.?

   ☐ Yes ☐ No

   If Yes, please explain:
   Click or tap here to enter text.

C. Participant Screening

1. Will participants be pre-screened before each in-person research activity for symptoms of respiratory infections? If yes, please describe the process you will use and who will do the screening and/or testing.
   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.

D. 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.

3. Does this location have a site safety plan for infection control?
   ☐ Yes ☐ No

E. Types of interaction

What types of participant interactions are involved in this study? For each type of participant interaction, describe what safety precautions will be in place (e.g., masks worn by researcher(s), masks worn by participant(s), limiting numbers of participants, other measures):

☐ One-on-one

Click or tap here to enter text.

☐ Gatherings (3 or more attendees)

Click or tap here to enter text.

☐ Naturalistic Observation indoors only (no interaction with people being observed)

Click or tap here to enter text.

F. 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. Do any of these groups have their own infection control protocols or requirements?
   Click or tap here to enter text.

4. Who has been involved in developing the Safe Research Plan?
   Click or tap here to enter text.

5. How many community members will the research team be in contact with?
   Click or tap here to enter text.

6. Please describe the safety protocols that will be in place during research events.
   Click or tap here to enter text.

G. Research Involving Indigenous Communities

Please complete Section F above and answer the following questions. If you are unable to affirm any of the statements below, the REB 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 infection control and/or contributed to the development of this safety plan.

H. Vaccination Status of Researchers

1. Are all health care workers who are members of the research team fully vaccinated, in compliance with Island Health requirements? If any member(s) of the research team who are required to have vaccinations prefer not to disclose their vaccine status, answer 'no' and consult with the REB by emailing ResearchEthics@islandhealth.ca.

   ☐ Yes ☐ No

If yes, please describe how you will confirm the vaccine status of all research team members who are required to be vaccinated (vaccine passport, verbal assurance, etc.).

Click or tap here to enter text.

2. Are other members of the research team encouraged to be fully vaccinated for influenza, COVID-19, and other respiratory diseases that are relevant to the region?

   ☐ Yes ☐ No

3. Please describe what precautions unvaccinated researchers will take to protect participants and others.

   Click or tap here to enter text.

I. Travel and Accommodation

If the answer to ANY of questions I-1 through I-4 is yes, please describe the mitigation strategies (self-isolation, PPE, etc.) that will be used to prevent spreading an outbreak between regions. If I-1 through I-4 are all answered No, please continue to section J.

1. Will the research team need to travel to any research sites?
   ☐ Yes ☐ No.
2. Will participants need to travel to any research sites?
   ☐ Yes ☐ No.
3. Will any members of the research team come from other locations (e.g., company representative, visiting collaborator)?
   ☐ Yes ☐ No.
4. Will some members of the local research team be travelling for other purposes not related to this research?
   ☐ Yes ☐ No.
5. Are any travel or health advisories in effect in the location(s) travelled to/from?
   ☐ Yes ☐ No.

6. 6. Will the traveller be required to self-isolate or take other protective steps (rapid antigen testing, using PPE, receiving vaccinations, etc.) before beginning research activity?
   ☐ Yes ☐ No.

   If Yes, provide details:
   Click or tap here to enter text.

7. 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 in the event of a new outbreak or epidemic.

☐ 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 develops respiratory infection symptoms?

If Yes, please describe:
Click or tap here to enter text.

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

K. Evolving conditions

1. Who will monitor PHO and Island Health guidance for information about regional outbreaks and updated requirements?
   Click or tap here to enter text.
2. 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 in-person research or travel.
   Click or tap here to enter text.

3. Have contingency plans or protocol revisions been developed in the event that a serious outbreak requires changing your in-person research activities?

   If Yes, please describe:
   Click or tap here to enter text.

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

L. Communications and Reporting

☐ I confirm that I will ensure monitoring of updated PHO and Island Health infection control guidance and comply with any requirements.

☐ I confirm that updated infection control guidance will be shared with the research team, participants, and other relevant parties.

☐ I confirm that Safety issues will be reported via a Request for Acknowledgement to the REB.

☐ I confirm that risks of infectious disease exposure during research are detailed in the informed consent form and/or script that will be provided to invitees/participants before they are asked to consent.

☐ I confirm that I will be responsible for maintaining the safety protocols, that any changes to the Safe Research Plan and/or study protocol will be submitted to the REB for approval, and that this information will be shared with the research team.

Click or tap here to enter text.	Click or tap to enter a date.
Principal Investigator Signature	Date