

Principles and Guidance for New and Resuming In-Person Research at UNBC During the COVID-19 Pandemic

The University of Northern BC is committed to supporting responsible in-person research based on the direction of the Provincial Health Officer (PHO) and the University's safety office. This document outlines the principles and instructions that **MUST** be followed when conducting in-person research to ensure the safety of research participants, faculty, students and staff. Please review this information carefully as you consider and plan your in-person research activities. This applies to those with new, resuming, or previously deferred studies.

During the COVID-19 pandemic, remote research activities continue to be recommended where possible for UNBC researchers seeking to conduct in-person research, a Safe Research Plan for their research project must be developed and submitted alongside their REB ethics application. These guidelines are intended to assist researchers in developing a Safe Research Plan. It is expected that safety considerations will differ from project to project, depending on the research methods and context, so the guidelines are not expected to act as a template. Although you may already have been required to submit a safety plan to your program or Dean for using UNBC facilities, the Safe Research Plan that you need to submit with your REB application is meant to ensure safe in-person participant-researcher interactions.

The virus that causes COVID-19 spreads in several ways: in droplets when a person coughs or sneezes; when someone touches a contaminated surface and then touches their face. The risk of person-to-person transmission increases the closer people are to one another, the more time spent near others, and the greater number of people are nearby. The risk of surface transmission increases the more people are in contact with the same surface and the more contacts happen over short periods of time.

Steps to completing and managing your Safe Research Plan

- 1. Review available guidance documents and resources that will inform your Safe Research Plan.
- 2. Assess the risks of your protocol and consider ways to mitigate risk in the context of COVID-19.
 - Consult with stakeholders, sponsors and participant communities as you draft your plan.
- 3. Draft safe research plan.
- 4. After drafting your plan
 - Attach the plan separately along with your ethics application for review by the REB, Office of Research, and Safety Office (See Appendix B – Approval Process and General Guidelines).
- 5. Once approved by the UNBC Safety Office, monitor and amend as needed.

Step 1 | Review Safety Guidance

Be aware that community guidelines, restrictions and practices may differ from the guidelines referenced above and will also need to be factored into your Safe Research Plan where applicable. For example, if you intend to carry out part of your research in a remote community or foreign country, you would need to consider specific requirements dictating the safe conduct of research in those locations. Researchers conducting research in these locations will be required to present documentation indicating that they

Guideline was adopted from the UBC Safe Research Plan Guideline and Template Jan 11, 2021

have approval to enter these communities and/or are following community specific guidelines/policies for things like quarantine/PPE, etc. UNBC will continue to monitor guidelines associated with conducting in-person research during COVID-19 so please watch for communications regarding the changing regulations.

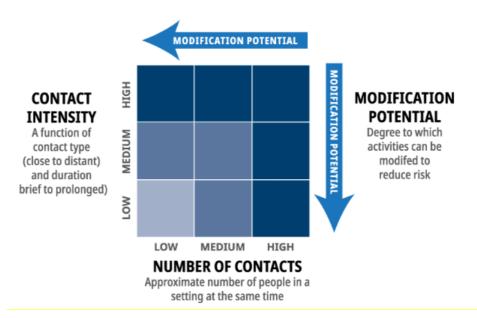
- a. Review relevant guidance from organizations such as:
 - the BC Center for Disease Control
 - Work Safe BC
 - The Government of Canada pages: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/measures-reduce-community.html#a3
 - o For guidance on vulnerable populations: https://www.canada.ca/en/public-health/services/publications/diseases-conditions/vulnerable-populations-covid-19.html
 - Coronavirus (COVID-19) and Indigenous communities: https://www.sac-isc.gc.ca/eng/1581964230816/1581964277298#chap1
 - The UNBC Office of Research website
- b. Review the First Nation/Inuit/Métis community websites for the regions where you intend to conduct research to gain the latest information about community status.
- c. Review other guidance specific to your profession or research area that could help with developing risk mitigation strategies.
- d. Ensure that you are aware of all relevant public health or other governmental or institutional policies, guidance and regulations pertaining to the location where your research is being conducted.

Step 2 | Assess the risks of your research in the context of COVID-19

Considering how, where and with whom your research will be conducted, what are the risks that COVID-19 may be transmitted either to participants or researchers? How can your research methods be modified to reduce risk? The guiding questions below will help you determine what kinds of risks might exist, based on the types of activities involved:

- a. **Contact Intensity** | What is the contact intensity of activities with study participants i.e. what is the type of contact (close/distant) and duration of contact (brief/prolonged)?
- b. **Number of contacts** | What number of contacts will occur in the activity setting i.e. how many people will be present in one setting at the same time? As a result of the mass-gathering events order¹, a group of over 50 would place the event in the high-risk category.

¹ See for more information: https://www2.gov.bc.ca/assets/gov/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/reports-publications/covid-19-pho-class-order-mass-gatherings.pdf



- c. Location and type of in-person interaction | What is the status of COVID-19 at the location of the research? What public health directives are in place? Please indicate if the status is unclear or incomplete and describe who has been consulted in the relevant jurisdiction. If confirmation is not available at the time of submission, the REB may decide to provide conditional approval only until confirmation can be received.
 - How many people will be required to be together in one place in order to conduct the research? How often will gatherings (2 or more) be required? How long will each interaction take?
 - Will physical distancing (2 meters apart) be possible in all aspects of the research? If it cannot be maintained is there protective equipment in place, e.g. plastic barriers and masks.
 - Is the research taking place at many sites? Is there a risk of research team members carrying the virus from one site to the next?
 - Is the research local, provincial, national or international? What are the relevant jurisdictions?
- d. **Methodology** | What methodology(ies) does the research utilize, e.g. observation, ethnographic participant observation, interviews focus groups, participatory community-based research? What risks are inherent in those you are using?
- e. **Travel and Accommodation** | Does the research involve travel by participants or researchers?
 - Who is required to travel, by what methods, for how long and how often?
 - If the research team is travelling internationally, are they required to self-isolate on arrival?
 - Is travel to smaller or more remote communities required? If so, what health services are in place and would they have the capacity to handle a COVID occurrence? If you are unable to determine the health infrastructure, and are unable to find an alternate location for conducting the research, you are advised to delay submitting your ethics application until reliable information can be provided by the community.
 - Does the research require overnight or longer stays for participants or team members?
 - Do available accommodations allow individuals to self-isolate if needed?

f. Surfaces and Equipment

Does the research involve sharing any equipment, tools, documents etc.?

• Will the research be conducted in a space that has surfaces that people may touch often, e.g. doorknobs, elevator buttons, desks?

Step 3 | Draft your Safe Research Plan and submit to the REB

The Safe Research Plan form is included below, and a fillable "Safe Research Plan Template" document is available for download at the same website location as these guidelines. Please ensure the following sections are included, as needed.

Introduction

- Name of the PI and if a Graduate or Under Graduate Student, include the name and department of the Faculty Supervisor
- Department / Faculty
- Study Jurisdiction (name the province/state/country that sets the public health guidelines for your research area). Justification as to why in person needs to be done over (preferred) remote methods must be provided.
- Study Setting/s (if study location is general, e.g. outside in a park chosen by the participant, please state this)
- Proposed date when in-person contact with participants will start or resume

Research Protocols

Describe protocols being put in place to reduce risks of person-to-person or surface transmission. Examples are provided below. **Please only include those that apply to your research.**

1. At-Risk Populations

Describe the risk profile of the research participant group (e.g., age, underlying medical conditions) and how risk will be managed for high risk members of the community.

2. Gatherings such as focus groups, collaborative meetings, presentations, research programs or events

Describe physical distancing arrangements.

- What limits have been placed on the number of people at a site or gathering at one time?
- What limits have been placed on the number and length of required in-person gatherings?
- Will gatherings be held outdoors or in a virtual format?
- What arrangements will be made in the space where gatherings are held to facilitate physical distancing requirements? For example: using furniture or other barriers; managing occupancy levels for bathrooms.

3. Community Based Research

Describe consultations with the affected communities. Consider the number of participants the researcher will be in contact with (also called the bubble).

- How will the impact of research on local communities be mitigated?
- What arrangements have been made to self-isolate for 14 days if necessary when traveling, particularly to areas with limited medical services?
- What arrangements have been made in advance for appropriate spaces to hold meetings, and to ensure cleaning protocols are in place? These arrangements should be overseen by the researcher.

4. Research Involving Indigenous Communities

Community Guidelines

Researchers will need confirmation from the community that it has the capacity to accept research activity (notwithstanding any agreements drafted pre-COVID). In addition to completing the Safe Research Plan, please also provide confirmation from a community representative that the community agrees to this research moving forward during this time.

Before attempting to engage, verify whether the Indigenous community has issued any guidance regarding their key contacts, capacity, and operations during COVID-19. These may be found on individual community websites, including on social media sites such as Facebook.

Coordinate with any other researchers known to be involved in the community to avoid duplicating outreach.

Use of Technology

To the extent that you are able to reach your contacts in Indigenous communities, you should work with them to determine whether the Indigenous community has the capacity to engage and their preferred method of engagement.

Although such engagement could be facilitated through the use of technology, communities or individuals within a community may not have the means (such as robust wifi) to connect. Familiarize yourself with any limitations in the community prior to engagement.

- Work with the local community to determine whether shared access to computer technology is available for those who may not have access in their homes, while ensuring that a protocol for maintaining public health guidelines (physical distancing) can be implemented.
- Discuss with the community, how to maintain regular yet respectful contact.
- Consider the extent to which you and your team may be able to support Indigenous (or remote)
 communities by providing surplus medical supplies, protective equipment, and other resources
 as part of a commitment to reciprocity.

Consider in the context of your research, postponing engagement activities until the pandemic is in a more manageable stage and Indigenous community capacity allows for meaningful engagement.

5. Interviews

Describe safety precautions being used if one-to-one interviews will be conducted in person:

- When conducting in-person interviews, you must describe in your safety plan how you will maintain physical distancing while at the same time ensuring privacy of conversations.
- Will non-medical masks be used by the researcher and participant? If yes, consider how their use may alter the ability to understand one another, or muffle a recording. If using masks, they should be provided by the researcher for participants. The purchasing any Personal Protective Equipment needed to conduct the research is the responsibility of the researcher.
- If recruitment is taking place in person, how will this be managed? Consider the perceptions of potential participants to being approached.
- How will interview schedules be maintained to ensure space between participants? Fewer interviews per time period may be necessary in order to allow time to disinfect surfaces between participants.

- o The researcher should provide basics like hand sanitizer for participants.
- o Washroom facilities must be available where interviews are held.

6. Travel and Accommodation

Describe how required travel will be managed.

- Limit the amount and duration of required travel whenever feasible.
- Researchers who have travelled internationally must self-isolate upon return.
- Many remote and Indigenous communities also require that outsiders undergo self-isolation before engaging with the community population. Researchers should ensure that they have the resources to abide by community requirements.
- If explicit guidelines are not in place, voluntary self-isolation prior to entering a remote area for the protection of the community under study is recommended.
- Limit the number of people travelling together in vehicles, ideally having only one person per vehicle or two, if 2-meter physical distance can be maintained.
- Reduce or eliminate the need for utilizing public transit for participants and researchers.
- Provide for separate accommodation if over-night stays are required.

7. Surface Transmission and Personal Protective Equipment

Describe how the risk of COVID-19 transmission will be mitigated in your research setting

- Be aware of infection prevention and control protocols implemented for the location where the research is being conducted, e.g. washrooms, elevators, doorknobs, etc.
- Follow the cleaning protocol provided by the facility.
- Consider whether cleaning supplies will be available.
- Develop personal hygiene rules e.g. washing hands or utilizing hand sanitizer at frequent intervals.
- Limit as much as feasible, shared equipment, material, tool, and hard copy documents.
- Have disinfectant supplies and strategies in place for hard surfaces (equipment includes pens, computers, tablets). Refer to WorkSafe BC and BC CDC websites specifically for guidance on adequate sanitation and appropriate PPE use.

8. Research Team and Participant Safety

Confirm that research team members have reviewed the information "Preventing COVID-19 Infection in the Workplace" and describe how your research team will interact to ensure safety, including as appropriate:

- Team composition: e.g. using the concept of "bubbles" or work teams to limit the number of people who will be interacting with one another.
- Steps that will be taken if a study team member or participant becomes sick or develops symptoms. The research team will be required to keep track of all contacts needed for contact tracing.
- Contingency plans for returning home or accessing care locally for research team members who experience worsening symptoms.
 - Prepare a self-isolation plan in advance in case team members become symptomatic while travelling.

- Will other team members be available to cover illness or provide support to a team member needing to isolate?
- What regular check-ins with team members will occur for the duration of the study?
- Self-assessment questions asked both of participants and researchers prior to in-person contact.
 Some suggested questions are:

1.	Do you have any of the following new or worsening symptoms or signs?
	☐ new or worsening cough
	 shortness of breath, sore throat, runny nose or nasal congestion, hoarse voice, difficulty swallowing
	☐ new smell or taste disorders
	☐ nausea, vomiting, diarrhea, abdominal pain
	☐ unexplained fatigue
	☐ chills or headache

- 2. Have you travelled outside Canada (or insert the country where research is being conducted) or had close contact with anyone who has travelled outside Canada (or insert country where research is being conducted) in the past 14 days?
- 3. Do you have a fever?
- 4. Have you had close contact with anyone with respiratory illness or a confirmed or probable case of COVID-19?

9. Communications

Describe what communication plans are in place for posting or disseminating your Safe Research Plan requirements

■ Is there a stated requirement that participants let the research team know if they develop symptoms? Will contact information for participants be retained in the event that follow up is needed? (Must be included in the informed consent). More information for participants in research during the COVID-19 Pandemic can be found in Appendix A, and should be shared in its entirety with participants before they consent to be involved in the study.

Step 4 | Disseminate, Monitor and Update your Safe Research Plan

- Distribute the Safe Research Plan to the research team.
- Make the plan available as a shared document. Team members can either provide a signature or email confirmation that they have read and understood the contents of the plan.
- Keep the Research Ethics Board aware of changes or unanticipated problems that arise during the research.
- Inform the REB of any required changes, protocol deviations, etc.

Northern Health-Partnered Research

Currently, Northern Health is not allowing in-person research to be conducted within their facilities, therefore, researchers will not likely get operational approval if they propose in-person methods. As stated on the Northern Health operational approval <u>form</u>, research must be conducted virtually at this time. The individuals allowed into a Northern Health facility are limited right now, and need to be considered "essential visits" (see NH <u>essential visitor policy</u> and <u>provincial guidance/poster</u>). In some

circumstances, in-person research may be possible depending on a number of factors. Researchers will need to work with NH knowledge users, team members and individuals providing operational approval to determine if and under what context this may be possible. NH encourages researchers to engage with operational approvers early in their research design to ensure proposed methods are feasible and research questions are aligned with NH priorities.

Safe Research Plan for new and resuming in-person research

PLEASE NOTE

- 1. The purpose of the Safe Research Plan is to demonstrate to the University that the necessary precautions and protocols are in place to protect research participants as well as the research team.
- 2. Please review the guidelines above before completing your Plan.
- 3. The Safe Research Plan is not intended to replace any safety protocols required by UNBC.
- 4. If a section is not applicable, indicate n/a.
- 5. The sections of the "Safe Research Plan Template" document posted to the same webpage as these guidelines are expandable. Use as much space as you need to explain the steps being taken to ensure the safety of participants and team members.
- 6. The Safe Research Plan should be a stand-alone document, so please ensure that you include all required details even if you have already provided this information in your Research Ethics Board application.

Introduction	
PI name	
Program	
Study Jurisdiction	[name the province/state/country that sets the public health guidelines for your research area]
Study Settings	[if study location is general, e.g. outside in a park chosen by the participant, please state]
Start Date	[Proposed date when in-person contact with participants will start or resume]

Suggested Details to include based on the Safe Research Guidelines

(Note - put "N/A" for sections that aren't relevant to your research)

Population Description

Describe the risk profile of the research participant group (e.g., age, underlying medical conditions) and how risk will be managed for high risk members of the community as they relate to the COVID pandemic. Contact tracing will change the privacy for participants and this needs to be acknowledged. Other general risks not directly related to COVID-19 and their mitigation should be described in Item #15 of the ethics New-Application and do not need to be repeated here.

[insert text]

Gatherings (focus groups, meetings, presentations, etc.)

Describe physical distancing arrangements and detail planned control measures

[insert text]

Research within community and healthcare settings

Describe who has been involved in developing the Safe Research Plan.

Please include all elements from Section 3 that apply to your research.

[insert text]

Research Involving Indigenous Communities

Indicate in your Safe Research Plan if your research involves Indigenous communities and describe who has been involved in developing the Safe Research Plan.

Letters of agreement (MOUs, etc.) will need to be attached to the ethics application before approval can be granted.

Please include all elements from Section 4 that apply to your research.

[insert text]

Interviews

What safety precautions will be taken for in-person interviews?

Please include all elements from Section 5 that apply to your research.

[insert text]

Travel and Accommodation

Describe how any required travel will be managed both for members of the research team and participants.

Please include all elements from Section 6 that apply to your research.

[insert text]

Surface Transmission and PPE

How will the risk of COVID-19 transmission be mitigated in your research setting?

Please include all elements from Section 7 that apply to your research. (Have you developed sanitization procedures for all shared equipment and touchpoints in the research location? Have you removed all unnecessary items such as magazines, flyers, office supplies in the research location?)

[insert text]

Research team member and participant safety protocols

What interactions will the research team and research participants have with each other?

Please include all elements from Section 8 that apply to your research.

Confirm whether self-assessment questions or other methods of assessment will be used.

[insert text]

Communications

Describe how your Safe Research Plan will be distributed to fellow researchers and participants.

Researchers must retain records for the purposes of research and also contact tracing, which must be communicated to the participants.

Please include all elements from Section 9 that apply to your research.

[insert text]

Reporting [See Step 4 in the Guidance]

Describe how adherence to the Safe Research Plan will be ensured

- How will changes to the plan be recorded?
- How will safety issues be reported?
- Who will be responsible for maintaining safe research protocols?

[insert text]			

Appendix A:

Notice of COVID-Related Risks during Research

Please read this form before you consent to participate in a research study. Please also talk to the researcher about any concerns you have before signing the consent form or agreeing to participate in the research. Remember that research participants may withdraw from a study at any time, without giving a reason.

Contact Tracing

The researcher may be required by public health authorities to share your contact information if there is a chance that you have been exposed to COVID-19 during a study visit. You will find more information about contact tracing on the BC Centre for Disease control website: http://www.bccdc.ca/health-info/diseases-conditions/covid-19/self-isolation/contact-tracing.

How does contact tracing work?

If public health authorities ask the researcher to provide a list of people who they have been in contact with, the researcher will be required to share your contact details. The researcher will not share information about the purpose of your contact, the name of the study, or anything about the research topic. Your contact tracing information will be kept securely and separate from de- identified research records and will be deleted 30 days after your last contact with the researcher It is important to know that because of this your anonymity will not be preserved.

What if I want to withdraw from the study?

If at any time you decide to withdraw from the study, the research team will only continue to store your contact information for as long as required by public health authorities. Other data you have contributed will be removed from the study when you withdraw.

Risks of in-person contact during the research

For research that involves in-person activities such as focus groups, interviews or observations, the researchers will be following safety plans that have been approved by the University. They include: safe use of facilities (including outdoor spaces), experimental equipment, personal protective devices, and physical distancing.

If you are required to use public transit to get to or from a research location, this may increase your risk of being exposed to COVID-19. We encourage you to take all precautions, including wearing a face mask while in public, washing your hands, avoiding touching your face, and keeping a safe physical distance from others (at least 2 metres or 6 feet). Please let the researcher know if you want more information about the safety plans that have been put in place.

What if I have COVID-19 symptoms or am diagnosed with COVID-19?

Before every research activity, the researcher will ask each person who is present a series of questions about their health. The questions have been recommended by public health authorities, and ask about physical symptoms, if you have been in contact with people who are sick, and other questions. Based on your responses, the researcher will decide if it is safe to proceed with the in- person activity.

Ensure that you keep the research team's contact information (included on the consent form) so you can share it with public health authorities in the event that you become sick after participating in research.

Appendix B:

Approval Process

- 1. Safe Research Plan (SRP) is submitted separately along with REB application
- 2. REB triages SRP to OR staff for review
- 3. OR staff ensures it is complete (works with applicant if needed)
- 4. OR staff shares completed SRP with Safety Office
- 5. Safety Office reviews and approves/rejects
- 6. Safety Office returns to OR staff
 - a. If approved, OR staff sends SRP (with approval) to REB and REB notifies researcher when REB application decision is made
 - b. If rejected, OR staff works with applicant to revise then proceed to Step 4, and so on.

General Guidelines

- Researchers should regularly review information provided by <u>UNBC</u> for research-related updates in response to COVID-19.
- As research teams prepare to increase research activities, supervisors must review safety
 protocols with regard to COVID-19 and provide training on the appropriate use of PPE, especially
 proper removal and disposal of gloves.
- If at any time a member of a research team is presenting with COVID-19 symptoms or feeling ill, they should immediately report this to the supervisor and the researcher should stay home.
- Researchers must regularly wash their hands according to PHO guidelines including when they enter and leave a research facility, and when returning home at the end of the day.
- All common areas and surfaces used by research teams should be cleaned regularly as well as at the start and end of each day. Cleaning and disinfecting information can be found here.
- The UNBC Research Ethics Board (REB) and Secretariat on Responsible Conduct of research have been providing direction on interview-based research and other research involving human subjects since the start of the pandemic. Updates can be found here. Just a reminder that changes to research protocols that involve human subjects need to be documented as amendments, submitted and approved by the REB. If a change is needed immediately to reduce risk or eliminate an immediate hazard, submit changes made to the protocol as soon as practicable.
- It is also possible that should infection rates increase, pandemic management directives may again become stricter. Therefore, timing and duration of your planned interviews is an important consideration.