

Safe Research Guidelines for In-Person Behavioural Research (New and Resuming) During the COVID-19 Pandemic

Researchers seeking to conduct in-person research must develop a Safe Research Plan for their research project and submit it with 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 department for using USask facilities, the Safe Research Plan you submit to the REB is intended to provide reviewers with more details specific to the conduct of the research and its impact on participants. The department safety plan is meant to ensure safe use and access of USask campus 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. After drafting your plan
 - Attach to your ethics application or amendment for review by the REB
4. Once approved, monitor and amend as needed. Any material changes to the plan will require approval from the REB via the Amendment process.

Step 1 | Review Safety Guidance

Be aware that community guidelines, restrictions and practices may differ from the guidelines referenced below 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.

- a. Review relevant guidance from organizations such as:
 - the [Government of Saskatchewan Website](#)
 - [Saskatchewan Advisories on events and locations of COVID-19](#)
 - The Government of Canada pages: <https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/measure-reduce-community.html#a3>
 - 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 [University of Saskatchewan COVID-19 Updates and Resources](#)
 - [International SOS](#)
- 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

Vulnerability of human participants in context of COVID-19

The COVID-19 public emergency raises the baseline of vulnerability for all people. However, for some individuals and communities, ongoing and new circumstances may exacerbate vulnerabilities even further. Researchers should assess participant vulnerability in terms of the following factors.

- Physical/physiological – attributes that put individuals at greater risk of morbidity and/or mortality from the disease (e.g., age, other diseases, immune system status)
- Psychological/emotional – attributes that may exacerbate mental health issues (e.g., obsessive-compulsive disorder, anxiety, depression) because of the pandemic, including pandemic directives and preventative measures (e.g., isolation, subjective fears)
- Social – attributes that put individuals at greater risk of exposure, of obtaining knowledge for prevention, taking preventative measures, obtaining treatment, and/or being able to maintain the health and life of others in their household or community (e.g., lack of space, food and water insecurity, unemployment, poverty, dependants)

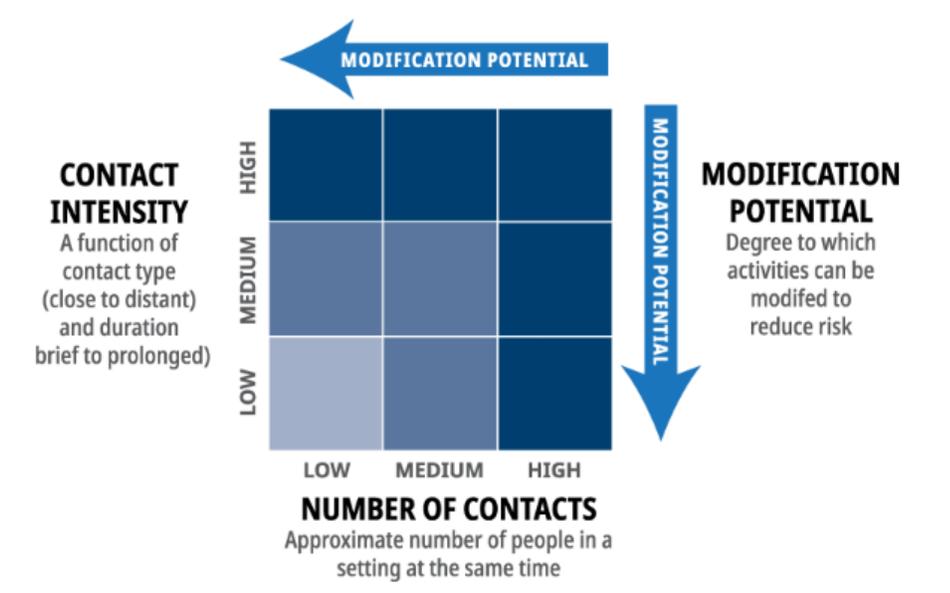
A combination of these factors may contribute to a participant’s circumstances. Researchers should consider the highest level of vulnerability for their participant group when completing or amending their ethics protocol, obtaining informed consent and conducting the research.

When researchers ask volunteers, who may not benefit from the research, to participate in face-to-face research the volunteers are not only taking additional risks during the encounter, but also during the act of travelling to the location or meeting the researchers at a specific location.

Consider 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://www.saskatchewan.ca/government/health-care-administration-and-provider-resources/treatment-procedures-and-guidelines/emerging-public-health-issues/2019-novel-coronavirus/public-health-measures/public-health-orders#current-public-health-orders>



- 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.
- 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 metres 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?
 - Is there a risk that research team members or participants may be exposed to the virus while in transit (e.g., on public transit, airlines)?

- If the research team is travelling internationally,
 - What is the infection rate in the country?
 - Are researchers allowed to enter the country to conduct research?
 - What are the legal and public health requirements for the location and participant populations?
 - Does the region have appropriate and adequate PPE in addition to other infection prevention and control precautions in place?
 - What are the screening and reporting requirements for participants and researchers? What are the risk implications of having contact information on participants in the research?
 - How will the researcher travel to the area and what risks will mode of travel carry for the researcher and participants?
 - Are researchers required to self-isolate on arrival?
 - Is there a mandatory quarantine period on returning home?

- 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?

- g. **Privacy and Confidentiality**
 - Personal health information may be collected through COVID-19 screening protocols. Contact information will be collected should a participant or researcher test positive to COVID-19 to facilitate prompt contact tracing. Guarantees of anonymity cannot be made for this reason. Researchers and REBs should consider the potential consequences that providing names to Public Health could potentially have with respect to risk if disclosed. This should be made clear to all participants

- Researchers should store contact information separately from de-identified data and maintain confidentiality to the extent otherwise described in the protocol.
- Maintaining two meters between researchers and participants, and/or speaking through masks may increase the likelihood that conversations may be overheard. Researchers should not guarantee privacy in such circumstances.

Step 3 | Draft your Safe Research Plan and submit to the REB with other approval documents

An [optional template](#) is available, but other forms are acceptable. Please ensure the following sections are included, as needed.

Introduction

- Name of the PI
- Department / Faculty
- Study Jurisdiction (name the province/state/country that sets the public health guidelines for your research area)
- 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. Comment on the risk to third parties (e.g. other members of their household or bubble).

2. Research requiring Physical Interaction

If the research requires physical interaction or intervention (e.g., touching to collect biometric data, physical manipulation, or collection of biological materials);

- Is there appropriate and adequate PPE available for both researcher and participant?
- What is the extent of the physical interaction and the associated risks (e.g., attaching biometric equipment to the participant vs. conducting dental exam)?

- Have you exhausted all physically distanced / contactless approaches to the task?

3. 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.
- Will non-medical masks or other PPE be used by the researcher and participants? If yes, consider how their use may alter the ability to understand one another, or muffle a recording. If using masks or PPE, they should be provided by the researcher for participants.

4. 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).

- What is the infection rate in the respective community, city, province or country?
- Are researchers allowed to enter the country/region and conduct research? What arrangements have been made to self-isolate for 14 days when traveling, particularly to areas with limited medical services?
- How will the impact of research on local communities be mitigated?
- 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.

5. 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 video-conferencing and virtual town halls using USask resources, 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.

6. Interviews

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

- If interviews are held in public spaces, how will you 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.

- Comment on how physical distancing and the use of masks may impact privacy.
- 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.
 - The researcher should provide basics like hand sanitizer for participants.
 - Washroom facilities must be available where interviews are held.

7. **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.

8. **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)
- For information on personal protective equipment: [USask PPE](#)

9. **Research Team and Participant Safety**

Confirm that research team members have completed the mandatory online training "COVID-19 Health and Safety"

(<http://safetyresources.usask.ca/services/training/index.php>) 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.
- 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?
- Your plan for contact tracing and communication, if any participants or researchers exhibit symptoms during or after the project. This should include how long you will retain participants' contact information for the purposes of advising participants about possible exposure to infection. You should also include in the consent form language advising participants to contact you, if they exhibit any symptoms after their participation or become aware of exposure to infection that may have allowed for transmission to a researcher or other participant.
- Self-assessment questions asked both of participants and researchers prior to in-person contact with a clear indication of the consequences for any affirmative answers (e.g., suspension of the individual's involvement in data collection until they receive a negative test result). 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? Or to a community under a public health advisory.
 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?

10. 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.)
- Be sure that the information in the relevant consent forms incorporates any pandemic measures in place that may affect participation (e.g., the need for PPE, the retention of contact information for contact tracing).

11. Consent Documents: COVID-19 Wording

The information below should be embedded, as relevant, in the various sections of consent documents or may be provided as a stand-alone section.

- Research site is located [insert], under the jurisdiction of [location] public health. We are taking all safety precautions to reduce the risk of spread of COVID-19 and expect you to follow public health directives as well.
- If you feel that you are from a vulnerable group with respect to COVID-19 effects (e.g., senior, immuno-compromised), please discuss your participation with the research team before consenting. You are under no obligation to participate and nothing bad will happen if you change your mind about participating in the research.

- the following safety protocols must be followed:
 - Screening – as per requirements for persons coming onto campus.
 - Take appropriate precautions (e.g. face covering / cloth mask) if taking public transportation and entering public indoor spaces.
 - Wash your hands upon coming onto campus / entrance to building. Hand sanitizer will be made available to you.
 - Physical distancing will be maintained, at all times, and if possible, wear a face covering / cloth mask. Otherwise we will provide you with PPE.
- We will be collecting personal contact information that we must retain in order to follow up with you and/or conduct contact tracing if you may have been exposed to COVID-19 in coming to the research site.
- Contact information will be kept separate from data collected through the research study to allow for de-identification of the research data (if applicable, as detailed in the protocol).
- You maintain your right to withdraw from the study at any time, including research data (if applicable). If you do withdraw, we will continue to maintain your contact information and will only give it to Occupational Health if required for contact tracing.
- We cannot guarantee anonymity as the personal contact information identifies you as a participant.

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.