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Steps to completing and managing your Safe Research Plan for In-person Research

- You must first provide justification for why the study cannot proceed remotely and should be done in-person
- Review available guidance documents and resources that will inform the development of your Safe Research Plan.
- Assess the risks of your protocol and consider ways to mitigate risks in the context of COVID-19. Consult with stakeholders, sponsors and participant communities as you draft your plan.
- After drafting your plan:
 - o Submit to your Department / Division Supervisor
 - Attach to your ethics application for review by the REB
- Once approved, monitor and amend as needed

1. Justification for In-Person

- Research time sensitive
- Pressing need for research
- Alternative not available or appropriate
- Research relates to COVID-19
- Other (provide justification)

2. Safety Guidance and Practices

You should follow the Yukon's Chief Medical Officer of Health (CMOH) guidelines at all times for current information. Community guidelines, restrictions and practices may also need to be considered. The understanding of COVID-19 is continually evolving and you should keep informed of other recommended practices to ensure safety. Some additional guidelines are referenced here and may need to be included in your Safe Research Plan where applicable.

Review relevant guidelines from organizations such as

- Yukon Government COVID-19 information https://yukon.ca/en/covid-19-information.
 Some considerations include:
 - o The Safe 6
 - o <u>Vulnerable populations: COVID-19 guidance</u>
 - o Orders and directions: COVID-19
- Government of Canada
 - Coronavirus disease (COVID-19): Guidance Documents
 https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents.html

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- Vulnerable populations and COVID-19 https://www.canada.ca/en/public-health/services/publications/diseases-conditions/vulnerable-populations-covid-19.html
- o Coronavirus (COVID-19) and Indigenous communities https://www.sac-isc.gc.ca/eng/1581964230816/1581964277298#chap1
- Yukon University COVID-19 response information https://www.yukonu.ca/covid-19
- International SOS

Consult with First Nations in Yukon communities that would be involved to determine the latest information on their community status.

Review other guidance that might help with developing mitigation strategies.

Ensure you are aware of all relevant public health or governmental or institutional policies, guidance and regulations pertaining to the location where your research is being conducted.

3. 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 following are guidance questions to help determine what kinds of risk might exist.

- a. Contact intensity what is the contact intensity of activities with study participants (close/distant) and duration of contact (brief/short/prolonged)?
- b. Number of contacts what number of contacts will occur in the activity setting
 should not exceed recommendations for groups,
- c. Location and type of in-person interactions What is the status of COVID-19 at the location of research? What public health directives are in place?
 - How often will gatherings (2 or more people) be required? How long will each interaction take place?
 - Will physical distancing (2 metres apart) be possible in all aspects of the research? If it cannot be maintained what is the plan to ensure protective equipment in place?
 - Is the research taking place at more than one site? Would it be possible for researchers to carry the virus from one site to the next?
- d. Methodology: What methods does the research use (i.e. observation, interviews, focus groups, participatory community-based research, etc.). What risks are there with the methods to be used?
- e. Travel and Accommodation: Does the research involve travel by participants or researchers? Researchers must consider YukonU travel restrictions.



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- Who is required to travel, by what methods, for how long and how often?
- Any self-isolation requirements at destination?
- 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?
- Does the research require overnight or longer stays for participants or researchers?
- Do available accommodations allow individuals to self-isolate if needed?
- f. Surfaces and Equipment
 - Does the research involve sharing equipment, tools, documents, etc.?
 - Will the research be done in a space that has surfaces that people may touch often (doorknobs, desks, etc.)?

4. Submit Safe Research Plan to Department/Division Head

Template provided to assist with drafting a Safe Research Plan. This is for guidance and can be modified to suit for your research.

Ensure that the following sections are included:

Introduction (name of PI, Department, Division, Section, Study location, study setting, proposed dates for start of in-person contact, REB # (if provided)

Research Protocols in place to reduce risks of person-to-person or surface transmission. (only include those that apply to your research)

- a. At-Risk Populations risk profile of research participants and how risk is managed
- **b.** Gatherings such as focus groups, collaborative meetings, presentations, research programs or events describe physical distancing arrangements and number of participants
 - Limits on number of people at site or gathering at one time
 - Limits on number and length of required in-person event
 - Arrangements in the space where gatherings are held to facilitate physical distancing requirements.
- **c. Community Based Research** describe consultations with the affected communities. Consider the number of participants the researcher will be in contact with.
 - What arrangements have been made to self-isolate for 14 days if necessary when travelling?

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• What arrangements have been made in advance for appropriate spaces to hold meetings, and ensure cleaning protocols are in place?

d. Research Involving Indigenous Communities

For work in Yukon communities you will need to have the appropriate approvals from any Yukon First Nations.

Community guidelines and requirements – need to confirm that community has capacity to accept research activity with COVID-19 considerations. Researchers should provide confirmation from community representative(s) that the community agrees to this research moving forward at this time. Before attempting to engage, verify whether the community has issued any guidance regarding their key contacts, capacity and operations during COVID-19.

Use of technology – Determine whether the community has the capacity to engage and their preferred method of engagement. Even if engagement could be facilitated through video-conferencing or virtual events using YukonU resources, communities or individuals within a community may not have the means (such as adequate internet services) to connect. Determine any limitations in the community prior to engagement.

- Work with local community campuses or other organizations to determine
 whether shared access to computer technology is available for those who may
 not have access, while ensuring that a protocol for maintaining public health
 requirements can be implemented (physical distancing).
- Discuss with the community, how to maintain regular, 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 for mutual
 benefit.
- Consider the current situation of the pandemic and if necessary, postpone engagement activities until safe and meaningful engagement is possible.

Describe how you are planning to address these considerations / requirements in your research.

- **e. Interviews** Describe the safety precautions being used if one-to-one interviews will be done in-person.
 - If interviews are held in public spaces, how will you maintain physical distancing while at the same time ensuring privacy of conversations?



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- Will non-medical masks be used by researcher and participants? If yes, consider how their use may alter the ability to understand one another, or muffle a recording. If using masks, will the researcher provide these to the participants?
- If recruitment is taking place in person, how will this be managed?
- How will interview schedules be maintained to ensure space between participants? (for example there might be fewer interviews per time period may be needed in order to allow time to disinfect surfaces between participants).
- Is the researcher providing hand sanitizer for participants?
- Are there washroom facilities available where interviews are held?
- f. Travel and Accommodation Describe how required travel will be managed.
 - How will Chief Medical Officer of Health guidelines be followed during travel?
 - Are there any community-specific travel restrictions in place?
 - Some considerations include:
 - Limit the amount and duration of required travel whenever feasible.
 - Researchers traveling outside the Yukon must self-isolate upon return (with the exception of travel from BC).
 - Confirm that communities do not require that outsiders undergo selfisolation before engaging with the community population. Researchers must ensure that they have the resources to abide by community requirements.
 - Limit the number of people travelling together in vehicles, ideally having only one person per vehicle, or two and have passengers wear masks in vehicles.
 - Provide for separate accommodation if over-night stays are required.
- **g. Surface Transmission and Personal Protective Equipment** Describe how the risk of COVID-19 transmission will be mitigated in your research setting.
 - What infection prevention and control protocols will be in place for the location where the research is being conducted? (washrooms, door handles, etc.).
 - What cleaning protocols will be provided by the facility?
 - What cleaning supplies will be available?
 - What personal hygiene rules will be developed? (e.g. washing hands or using hand sanitizer at frequent intervals).
 - How will you limit shared equipment, materials, tools and hard copy documents?
 - Have disinfectant supplies and strategies been put in place for hard surfaces? (equipment, pens, computers, tablets, etc.).



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- h. Research Team and Participant Safety confirm that research team members have completed training and describe how your research team will ensure safety. Courses available for anyone: Workplace Safety and Prevention Services "Coronavirus Preparedness for Employers and Employees" https://www.wsps.ca/Shop/Training/E-Courses/Coronavirus-Preparedness-Employers-Employees-Eng.aspx or Canadian Centre for Occupational Health and Safety "Pandemic Planning: Reopening for Business." https://www.ccohs.ca/products/courses/pandemic-reopening/.
 - Team composition have steps been taken to limit the number of people who will be interacting with one another?
 - What steps will be taken if a study team member or participant became sick or develops symptoms?
 - What are the contingency plans for returning home or accessing care locally for research team members who experience worsening symptoms?
 - Do you have a self-isolation plan in case team members become symptomatic while traveling?
 - Will other team members be available to cover illness or provide support to a member needing to isolate?
 - What regular check-ins with team members will occur for the duration of the study?
 - Do you have self-assessment questions to be asked both of participants and researchers prior to in-person contact? An online self assessment tool is available through Yukon Government at https://service.yukon.ca/en/covid-19-self-assessment/. Self-assessment question examples for participants and researchers prior to in person contact:

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
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- 2. Have you travelled outside Canada or been in contact with anyone who has travelled outside Canada 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?
- i. **Communications** describe what communication plans are in place for posting or disseminating your Safe Research Plan requirements. Clear details are required on



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what should be done if anyone involved develops symptoms or is in contact with someone with symptoms.

j. Consent Documents: COVID-19 considerations

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

- Research site is located [insert location], 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 (for example seniors, immune-compromised etc.), 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
 - Take appropriate precautions (e.g. face covering / cloth mask)
 - Washing hands upon arrival to research location. 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 data (if applicable)
 - 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 Yukon Health if required for contact tracing.
 - We cannot guarantee anonymity as the personal contact information identifies you as a participant.

4. Dissemination, Monitoring and Maintaining your Safe Research Plan

- Distribute to the team and get confirmation they have read and understood the contents
- Ensure REB is informed.
- Keep REB aware of any changes or unanticipated problems that arise during the research.