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Non-Clinical Guidelines for New and Resumption of In-Person Research

The COVID-19 pandemic, the introduction of vaccines and the recent surge of the Delta variant have significantly affected human participant research for the foreseeable future. As research activities resume, they must follow the recommendations of Alberta's Chief Medical Officer of Health, whether the research is conducted on campus or not. Where the research is conducted on campus, University safety measures general directives must also be followed. COVID transmission risks must be part of the ethical considerations for the approval of any human participant research. To reduce risks for all, research activities should be moved from in-person interactions to remote interactions as much as possible. Where in-person interactions are necessary they must include risk mitigation strategies and participants must be advised of risks as part of the consent process.

These guidelines are intended to assist researchers in identifying risks and developing plans to minimize their impact. Safety considerations will differ from project to project, depending on the research methods and context. These guidelines are intended to provide the Research Ethics Board (REB) and the research team with details specific to the conduct of the research and its impact on participants. That is, to ensure safe in-person participant-researcher interactions.

These identified risks should be communicated to the REB in Section 3.1 of the ARISE application along with any mitigations strategies. Given the fluid nature of the pandemic and evolving requirements, it is sufficient to state in your ethics application that any mitigation strategies will conform to the prevailing guidelines. Any changes to the consent process should also be communicated with updated documents appended to the application as applicable.

When conducting in person research

The researcher has an obligation to mitigate the risk of infection to research participants. To mitigate Covid-19 risks:

1. Researchers should conduct a personal health assessment each day that they conduct research and stay home if they feel ill.
2. Researchers who can be safely vaccinated should be fully vaccinated before commencing research. Effective October 4, 2021, anyone coming to campus will be required to be fully vaccinated.
3. Review all available guidance documents and resources.

4. Assess the risks of your research procedures and methods and consider ways to mitigate risks.
5. Consult with stakeholders, sponsors and participant communities.

Review Safety Guidance

Be aware that community guidelines, restrictions and practices may differ and will need to be considered 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 Canada pages: <https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/prevention-risks/measures-reduce-community.html#a3>
 - Coronavirus (COVID-19) and Indigenous communities: <https://www.sac-isc.gc.ca/eng/1581964230816/1581964277298#chap1>
 - [University of Alberta COVID-19 \(novel Coronavirus\) Information](#)
 - [COVID-19 Info for Albertans](#)
 - [International SOS](#)
- b. Review 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.

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?

- **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 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?
- c. **Vaccination Status** | What is the current vaccination status of the population you will serve? Are research staff fully vaccinated? Research conducted on campus will require that all visitors are fully vaccinated.
- 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 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?

Other Considerations

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, children under 12 years of age and not eligible for vaccination) 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.

- 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). Researchers should confirm with 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, 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:

- 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.
- If recruitment is taking place in person, how will this be managed? 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 should 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.
- 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, pens, computers, tablets)

8. **Research Team and Participant Safety**

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?
- 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?
 - 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 safety plan:

- 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.)

Changes and Updates to this Plan

- All members of the research team should be aware of these plans and any changes as they occur.
- Keep the REB aware of changes or unanticipated problems that arise during the research.
- Inform the REB of any required changes, protocol deviations, etc.