In-person Research with Human Participants Under COVID-19 Restrictions

Community (off-campus) Research\(^1\) - Instructions for Human Research Ethics

Purpose

This document outlines instructions for the safe and gradual resumption of in-person research activities with human participants in community (off-campus) research under the Human Research Ethics Board (HREB) to minimize the spread of COVID-19 during the global pandemic.

These instructions apply to community (off-campus) research involving human participants in clinical and behavioural research conducted in locations and sites off-campus – locally, regionally and internationally.

In-person community research activities involving research participants and communities carry the risk of COVID-19 transmission. Such in-person, face-to-face activities include but are not limited to: recruitment, data collection activities, use equipment or devices on/with participants, in-person interventions with participants, face-to-face observations of participants, collection of human biological samples etc.

- Please refer to the Annotated Guidance for In-person Research During COVID-19 when completing Human Research Ethics COVID-19 requirements described in this document.
- In-person research activities also includes research activities with research team members and partners, research consultations, debriefings and engagement with Indigenous nations, partner organizations etc.\(^2\)
- Instructions for On-campus Research are in a separate document.

Community (off-campus) Research

For the purpose of this document community research applies to research involving human participants conducted in locations, sites, or spaces other than, or in addition to, the UVic campus. Community research includes but is not limited to research conducted in the following settings and locations with research participants:

- Public outdoor spaces (parks, streets, town squares)
- Private indoor and outdoor settings (homes, properties, offices, businesses)

\(^1\) For campus research with participants please see “On-campus Research”

\(^2\) This guidance applies to all in-person research activities with participants and entities reflected in the Human Research Ethics Standard Application Form, the Course-based Application Form and the TCPS2 (national human research ethics policy).
• Facilities or spaces under the jurisdiction or authority of an organization or entity (e.g., schools, community centers, other post-secondary institutions, government offices, ocean vessels, etc.)
• Health facilities and clinics under the authority of a health authority, hospital, health region, private practitioner/clinician
• Lands and facilities under the authority of an Indigenous nation(s) or community
• One or more geographical locations in a city, region or country

Research Ethics Review During Publicly Declared Emergencies

The Board’s operations are grounded in the *Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans* (TCPS2 2018), specifically Chapter 6 Research Ethics Review During Publicly Declared Emergencies (Article 6.23)

"[R]esearch ethics review during publicly declared emergencies is even more important than under normal circumstances, and may require even greater care, since everyone (participants, researchers and REB members themselves) may be rendered more vulnerable by the nature of the emergency” (p.88).

“Recognizing and respecting the principle of Justice means that research ethics review policies and procedures for publicly declared emergencies shall be used in a manner that is not discriminatory or arbitrary. The commitment to justice advances a fair and balanced distribution of risks and potential benefits even in the face of public emergencies” (p.89).

“The increased public risks and devastation that cause public emergencies to be declared can threaten autonomy and physical, emotional, institutional and social welfare or safety. They also bring inherent tensions and pressures that may impact deliberative decision making. Taking all of this into consideration, REBs [research ethics boards] and researchers should ensure that the risks and potential benefits posed by any proposed research are appropriately evaluated, including provisions for greater than normal attention to risk, where applicable” (p.89).

Information for Researchers: In-person Research

Researchers who propose to use in-person activities in community (off-campus) research during the COVID-19 pandemic restrictions are required to seek Human Research Ethics Approval for the following:

• Re-starting a previously approved study where in-person activities were paused during suspension of in-person research (via an amendment to the application³)
• Starting a study that was granted a Deferred Approval during suspension of in-person research (via revisions to the reviewed study)
• Adding in-person activities to an approved remote or virtual study (via an amendment to the application)
• Initiating a new study (via a new Standard Application Form or Course-based Application Form)

*See Study Status Table with researcher action scenarios at the end of this document.*

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³ Applies to paper-based studies and studies online in UVic-RAIS and the Provincial Research Ethics Platform
Instructions for Submitting Human Research Ethics Application and/or Amendments

(1) During the continued COVID-19 restrictions, use of remote methods for research involving human participants are the safest. Researchers are advised to continue to use remote methods (via telephone, online, emailing) or through virtual video conferencing platforms or meeting methods (e.g., Zoom, BlueJeans etc.) in lieu of in-person activities whenever possible. Please refer to the May 22, 2020 FAQ on Conducting Research Virtually with Human Participants.

(2) The HREB recognizes that, while it is feasible for some research projects to continue with, or switch over to remote activities, the characteristics of a given project and its context may limit the extent to which this is feasible.

The availability, accessibility and staffing levels etc. of partner or host organizations (while meeting their own COVID-19 safety requirements), may also limit the extent to which in-person research with participants is feasible.

The following steps are provided to assist researchers to apply for human research ethics approval for in-person research when remote methods are not feasible.

Note: Please be aware that it might not be possible (even with completion of these steps) to safely resume, amend, or initiate new in-person activities within current COVID-19 restrictions.

Researchers are required to complete the following steps:

A) Address the following sections in the Research Ethics Application Form. Use the Annotated Guidance for In-person Research During COVID-19 Restrictions to complete the following:

i. Explain the types and magnitude of risks in the “Risks and Mitigation” section of the application form to address risks and safety strategies both generally and specific to COVID-19:

RAIS Online Research Ethics Application Sections: “Level of Risk, Estimate Risk of Harm, Possible Risks, Risks to Researcher.”

Paper based studies use Request for Modification Form: Complete all questions in Section G “Level of Risk”

ii. Ensure the Participant Consent Form(s) include information to apprise participants of “COVID 19” risks and specific safety measures that you will put in place to protect study participants during the COVID-19 pandemic restriction period.

4 FAQ on Conducting Research Virtually with Human Participants
5 If you intend to switch all in-person activities to remote formats you are permitted to implement the changes before applying for an amendment to the study when the changes are necessary to eliminate an immediate risk to participants [TCPS2 Article 6.15]. You will be temporarily granted a maximum window of 10 business days to submit the amendment which will subsequently be reviewed.
iii. COVID-19 study information/updated information is required in the “Anonymity and Confidentiality” section of the application form to address limits to and strategies to maintain both generally and specific to COVID-19):

RAIS Online Research Ethics Application Sections: Anonymity, Confidentiality, Limits to anonymity and confidentiality.

Paper based studies use Request for Modification Form: Please address in section “Other Information.”

iv. Ensure the Participant Consent Form(s) include information to apprise participants of “COVID 19” specific public health contact tracing requirements and limits to anonymity and confidentiality, and measures that will be put in place to protect participants in the study during the COVID-19 pandemic restriction period.

B) Attach a study-specific assessment (Word document)

Provide a study-specific assessment of your project in a written summary or point form in a Word document. Attach or upload the assessment as an appendix to your research ethics application or amendment/modification.

Use the Annotated Guidance for In-person Research During COVID-19 Restrictions to prepare your assessment. Professional and standard practices/links may be included as applicable.

The study-specific assessment must address the following:

i. Justify: a) why it is absolutely necessary to use or resume in-person activities at this time and identify the specific in-person activities [Note: Convenience for participant and/or researcher is not sufficient justification]; or (b) which virtual/remote methods will continue to be used (if proposing a combination of in-person and virtual/remote methods during COVID-19).

ii. Confirm that you have reviewed at least one of the suggested public health sites about prevention and safety measures:
   - BC Center for Disease Control
   - BC Center for Disease Control - Dashboard for BC
   - Public Health Agency of Canada (Prevention and Risks)
   - WorkSafe BC (COVID-19 Safety Plan)
   - World Health Organization (Getting Your Workplace Ready)

iii. Identify the sections in your research ethics application where you propose to use in-person activities (e.g., recruitment, data collection, consent, dissemination etc.) and include relevant safety procedures from public health information from the above sites.

   Examples: physical distancing with masks during observations inside a facility, disinfecting of exercise machines, use of masks, physical distancing and cleaning building blocks between in-person observations of children, protocol for dropping off sterilized recording device to participants’ doorstep, cleaning devices when retrieved by research assistant etc.).
iv. Safety procedures and the study: Explain how your safety procedures are appropriately proportionate to the population, the duration and type of the proposed in-person activities, and the study’s context.

v. Vulnerability: Explain a) whether there have been changes to the vulnerability of participants since the start of COVID-19 and public health restrictions; b) whether participating in-person activities could elevate their vulnerability.

Some participant groups may be in more vulnerable health and safety situations because of the pandemic (people with underlying health conditions, elders, caregivers etc.) or they might be in precarious situations due to the effects of the pandemic (e.g., loss of income, mental health, bereavement etc.).

vi. Risk impacts and safety: Explain whether in-person research with participants will impact the safety of their family members, those living with the participants, and the immediate locale or community. If yes, provide a follow-up plan (e.g., in-person activity will be postponed or canceled if the researcher or participant is unwell and will follow health directives for self-isolation, testing etc.)

vii. Geographic-specific assessment: The pandemic’s prevalence and severity differs by city, region, province and nation. Infection rates fluctuate. Waves of infection, as well as participants’ and researchers’ access to testing and health care may also impact your study. Travel restrictions may apply depending on your study’s location(s).

Specify the city, region(s) or countries where your in-person research is to resume or is being proposed, whether the location(s) has sufficiently re-opened for safe in-person research activities, and the type of travel involved, if applicable. Confirm that you have, and will continue, to monitor pandemic advisories, new lockdowns, travel restrictions etc.

If in-person research involves travel to or within a region or country, provide information on modes of travel and access to health services. If you or research team members are currently based in a locale (such that there is minimum or no travel required) please specify.

viii. Contact tracing and potential impact on participant anonymity and confidentiality:
Explain your plan for maintaining confidentiality of participants within the context of potential contact tracing for and/or exposure to COVID-19 (e.g. participant contact information kept separate from the data collected). Include and explanation of how this information will be stated in your participant consent form(s).

In the event that a research participant or member of research team has been exposed to or tested positive for COVID-19 it may be necessary to report to the public health authority in whose jurisdiction the research has been conducted and/or in which the researcher or research team has traveled to enable contact tracing as this may be required in certain jurisdictions. This puts some COVID-19 specific limits on guarantees of anonymity and confidentiality of participants. Explain your protocol for maintaining confidentiality of participants within the context of contact tracing (e.g. participant contact information kept
separate from the data collected). Include how this information will be stated in the participant consent form.

For instance, is there a stated requirement that participants let the research team know if they develop symptoms? Will contact information for participants be stored in a separate file from research data in the event that follow up is needed? If yes, this information must be included in the informed consent.)


Anyone who is concerned that they may have been exposed to, or is experiencing symptoms of COVID-19 in BC, should complete the self assessment at https://bc.thrive.health/

C) In the study-specific assessment (Word document) address the following spheres (if applicable).

Use the *Annotated Guidance for In-person Research During COVID-19 Restrictions* to complete these sections:

**Sphere 1: Host or partnering organization(s) assessment**

Organizations hosting your research or partnering with your research team (e.g., schools, school districts, community organizations, private industry, government offices, etc. to carry out the study) might have additional/different research requirements, new access restrictions or their operations may be curtailed or closed.

Specify and provide documentation if available, or a justification if documentation is not available, of host organizations’ ongoing agreement to support or begin hosting in-person research activities. Explain changes to agreements/permissions and/or procedures approved by the Human Research Ethics Board prior to the moratorium on all in-person research that reflect any new COVID-19 safety requirements (including those from UVic and host organization).

**Sphere 2: Indigenous Nation(s) and communities’ assessment**

Specific Indigenous nations and communities might have additional and/or different restrictions on research and/or in-person visitors to their land or community offices or venues during COVID-19 restrictions.

Specify and provide documentation if available, or a justification if documentation is not available, of partner Indigenous communities’ ongoing agreement to host or continue to support in-person research activities. Explain changes to agreements and/or procedures approved prior to the moratorium on all in-person research that reflect any new COVID-19 safety requirements (including those from UVic and host organization).

Some communities have issued their own notices/restrictions about visiting their territories during the pandemic. Please provide any such notices with your study-specific assessment /
application so that the Human Research Ethics Board can assess how the plans for research do or do not align with the First Nation’s guidance.

**Sphere 3 : Health clinics, hospitals, health authorities assessment**

Health sites and locations might have curtailed research operations, introduced new access restrictions or are temporarily closed. Some may only focus on COVID-19 clinical research.

Specify whether health clinics etc. have agreed to support or are ready to continue to host in-person research activities at this time. Explain changes to agreements and/or procedures approved prior to the moratorium on all in-person research that reflect any new COVID-19 safety requirements (including those from UVic and host organization).

If the study involves in-person standard of care and/or the requesting of data access please clarify.
## Study Status Table – Community (off-campus) Research

### Researcher Action Scenarios

<table>
<thead>
<tr>
<th>Research Ethics Study Status Community (off-campus) Research</th>
<th>Researcher Action for Research Ethics</th>
<th>Address In-person research requirements from this document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiate new study that includes in-person research activities or components with participants, organizations etc.</td>
<td>Apply for human ethics approval for the new study</td>
<td>Attach study-specific assessment and applicable appendices</td>
</tr>
<tr>
<td>Study was issued a <strong>Deferred Approval</strong> during in-person research moratorium. Proposes to seek approval for in-person activity or components.</td>
<td>Resubmit the application to research ethics with your study-specific assessment and appendices. Application will be reviewed according to new in-person research requirements</td>
<td>Attach study-specific assessment and applicable appendices with your research ethics application</td>
</tr>
<tr>
<td>Approved study. Proposes to resume in-person activity or components</td>
<td>Apply for an amendment to the approved study</td>
<td>Attach study-specific assessment and applicable appendices with revisions or re-submitted ethics application</td>
</tr>
<tr>
<td>Renewing an approved study. Proposes to resume paused in-person activities or components.</td>
<td>Submit the renewal which will be processed. Apply for an amendment to the approved study</td>
<td><strong>Attach to ethics amendment</strong></td>
</tr>
<tr>
<td>Approved study. Proposes to change or add new in-person activity or components.</td>
<td>Apply for an amendment to the approved study</td>
<td>Attach study-specific assessment and applicable appendices</td>
</tr>
<tr>
<td>Approved study. Proposes to replace all in-person activities with fully remote activities</td>
<td>Implement remote modes immediately and apply for amendment within 10 days [6]</td>
<td>Study-specific assessment not required</td>
</tr>
<tr>
<td>Approved community study. Proposes to add <strong>on-campus in-person activities/components</strong></td>
<td>Apply for amendment to the approved study</td>
<td>Include study-specific assessment and attach approved <a href="#">on-campus Safe Work Plan</a> if on-campus activities continuing</td>
</tr>
<tr>
<td>No action required</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

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[6] If you intend to switch all in-person activities to remote formats you are permitted to implement the changes before applying for an amendment to the study when the changes are necessary to eliminate an immediate risk to participants [TCP52 Article 6.15]. You will be temporarily granted a maximum window of 10 business days to submit the amendment which will subsequently be reviewed.
<table>
<thead>
<tr>
<th>Approved study continues with remote/virtual activities only(^7)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved study. All in-person data collection, activities with participants and organizations and/or participant engagement have been completed.</td>
<td>No action required</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

\(^7\) ibid