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

On-Campus Research¹ - 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 research conducted on-campus in UVic labs, classrooms, other indoor facilities (e.g. gymnasia)², offices, and campus outdoor spaces etc. under the Human Research Ethics Board (HREB).

In-person research activities (e.g., use of specialized equipment on participants, in-person devices or computers for data collection, face-to-face interventions with participants, collection of human biological samples etc.) carry the risk of COVID-19 transmission.

- Please refer to the Annotated Guidance for In-person Research During COVID-19 when completing Human Research Ethics requirements described in this document.
- Although you may have or will submit a UVic Campus Safe Work Plan outlined in the UVic Principles and Guidance for the Resumption of On-Campus Research, these instructions are specific to the Human Research Ethics Board (HREB). They are intended to provide the Board reviewers with study-specific and procedural details about the conduct of your research for safe in-person participant-researcher interactions, particularly its holistic impact on participants, research team members and others.
- These instructions and the Annotated Guidance were created with input from Occupational Health, Safety and Environment.
- Instructions for Community (off-campus) Research are in a separate document.

Research Ethics Review During Publicly Declared Emergencies

The Board’s operations and requirements 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).

¹ Instructions for Community (off-campus) in-person research are in a separate document. ADD LINK
² Classrooms, buildings and some campus facilities (e.g., gymnasia) etc. may be closed or their use restricted. Researchers are advised to check with non-academic room bookings, the library or their department. See Annotated Guidance for In-person Research During COVID-19 Restrictions https://www.uvic.ca/research/assets/docs/Ethics/covid-19.annotated_guidance_in-person_research.pdf
“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).

In-person campus research activities include but are not limited to:

- Inviting participants to a campus space - indoor (e.g., classroom, office, lab) or outdoor (e.g., green space) - to be screened for study eligibility;
- Inviting participants to a campus space – indoor (e.g., classroom, office, lab, facility) or outdoor (e.g., green space) - for data collection;
- Recruiting individuals in a face-to-face manner on campus and/or to collect data from them during the interaction (e.g., hallways, green spaces);
- In-person research undertaken as part of coursework in in-person courses or course-based research (See Annotated Guidance);
- Non-UVic researcher conducting research in a campus facility or space (indoor or outdoor).

Information for Researchers: In-person Research and Campus Safe Work Plan

(1) Researchers who propose to use in-person activities on campus during the COVID-19 pandemic restrictions are required to seek Human Research Ethics Approval with an approved campus Safe Work Plan (SWP) ³ for the following:

- Re-starting a previously approved study where in-person activities were paused during the suspension of in-person research (via an amendment to the approved study) ⁴
- Starting a study that was granted a Deferred Approval during in-person research suspension period (via revisions to the reviewed study)
- Adding in-person activities to an approved remote or virtual study (via an amendment)
- Initiating a new study (via a new Standard Application Form or Course-based Application Form)

Please see Study Status Table with researcher action scenarios at the end of this document.

(2) An approved Campus Safe Campus Plan (SWP) must be submitted with your Human Research Ethics (HRE) Application. If SWP approval is not included, the HRE application will be returned and will not be reviewed. The UVic Principles and Guidance for Resumption of On-campus

³ In the case of research activities undertaken by students, Safe Work Plans are submitted by the faculty member (student’s supervisor) to Occupational Health, Safety and Environment

⁴ Applies to paper-based studies and studies online in UVic-RAIS and the Provincial Research Ethics Platform
Research During COVID-19 (June 12, 2020) contains principles and practices for all researchers who propose to conduct research during COVID-19 restrictions on campus including the procedures for completing and submitting a Safe Work Plan for approval. Please contact Occupational Health Safety & Environment if you have questions about the Safe Work Plan ohs@uvic.ca

(3) Human Research Ethics (HRE) Applications for on-campus in-person research will be reviewed in the priority order identified in the phased approach described in the UVic Principles and Guidance for Resumption of On-campus Research During COVID-19 (p.2).

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 safest⁵. 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.)⁶ 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 and context of a given project may limit the extent to which this 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 all 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. Refer to 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.”

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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 [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.

⁶ FAQ on Conducting Research Virtually with Human Participants
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.

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. See annotated guidelines.

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

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 complete your study-specific 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 based on public health information from the above sites.

Examples: use of masks, disinfecting of equipment, social distancing at computer lab observations, use of masks and one participant at exercise lab, disinfection of treadmill between participants, disinfection and use of masks for participant to collect blood sample at lab 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. Safety impacts: Explain whether in-person research with participants will impact the safety of family members and 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. 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 an explanation of how this information will be stated in your participant consent form(s).

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/
### Study Status Table – On-campus Research

#### Researcher Action Scenarios

If the approved Safe Work Plan (SWP) from UVic Occupational Health, Safety & Environment (OHSE) is not attached, the human research application will not be reviewed and will be returned immediately.

If re-locating in-person activities with participants from campus to the community, please follow the [Human Research Ethics Instructions for Community (off-campus) Research](#).

<table>
<thead>
<tr>
<th>Research Ethics Status On-campus in-person research</th>
<th>Researcher Action for Research Ethics for COVID-19</th>
<th>Approved Campus Safe Work Plan (SWP) from (OHSE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiate a new study that includes in-person research with participants</td>
<td>Apply for human ethics approval for the new study</td>
<td>Attach to new ethics application</td>
</tr>
<tr>
<td>Previously approved study. Researcher proposes to resume paused in-person activities or components.</td>
<td>Apply for an amendment to the approved study</td>
<td>Attach to ethics amendment</td>
</tr>
<tr>
<td>Study was issued a <strong>Deferred Approved</strong> during in-person research moratorium.</td>
<td>Resubmit the application to ethics office with your study-specific assessment. Application will be reviewed according to new in-person research requirements</td>
<td><strong>Attach to ethics amendment with revisions or re-submitted ethics application</strong></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>Attach to ethics amendment</td>
</tr>
<tr>
<td>Approved study. Proposed change to on-campus component (e.g., adding or adjusting on-campus data collection)</td>
<td>Apply for an amendment to the approved study</td>
<td>Attach to ethics amendment</td>
</tr>
<tr>
<td>Approved campus study. Proposed change to <strong>add community (off-campus) component</strong></td>
<td>Apply for an amendment to the approved study</td>
<td><strong>Attach approved SWP to ethics amendment</strong></td>
</tr>
<tr>
<td>Approved off campus study. Proposed change to <strong>add campus component</strong></td>
<td>Apply for an amendment to the approved study.</td>
<td><strong>Attach approved SWP to ethics amendment</strong></td>
</tr>
<tr>
<td>Approved study where changes <strong>do not</strong> impact campus procedures or spaces (e.g., adding a remote survey)</td>
<td>Apply for an amendment to the approved study</td>
<td><strong>SWP required for research staff returning to campus, not required for research ethics</strong></td>
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<tr>
<td>Approved study continues with remote/virtual activities only</td>
<td>No action required</td>
<td><strong>Apply for SWP. Approved SWP does not need to be submitted to research ethics</strong></td>
</tr>
<tr>
<td>Approved study where all in-person data collection, activities with participants have been completed</td>
<td>No action required</td>
<td>Not applicable</td>
</tr>
</tbody>
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7 As instructed by UVic Occupational Health, Safety and Environment