

<u>Human Research Ethics Board</u> <u>Annotated Guidance for In-person Research with Human Participants under</u> COVID-19 Restrictions

Purpose

This Annotated Guidance is a reference for researchers completing their research ethics applications (new applications and amendments) to meet **Human Research Ethics Board (HREB)** <u>requirements for in-person research activities during the pandemic</u> as outlined in the following HREB Instruction documents:

- Instructions for On-Campus Research with Participants During COVID-19 Restrictions
- Instructions for <u>Community (off campus) Research with Participants During COVID-19</u> <u>Restrictions</u>

Table of Contents

Researcher Requirements	3
Risks and Mitigations for Participant and Community Safety	3
Safety Practices	4
Vulnerability	4
Participant Anonymity and Confidentiality for COVID-19 Exposure and Contact Tracing	4
Research Team Safety and Communications with Research Team Members	5
Campus Classrooms, Offices and Libraries	5
Collection of Biological Samples	5
Course-based Research and Experiential Learning in Courses	6
COVID -19 Clinical and Public Health Studies to Alleviate the Pandemic	6
Engagement with Indigenous, First Nations, Métis and Inuit Peoples (New and Ongoing Studies)	7
Equipment and Devices for In-person Research	7
Non-UVic (external) Researchers	8
Research Involving Other Research Ethics Boards (including Research Ethics BC Harmonized studies) o	
Team members at Other Universities or Institutions	8
Travel	8
Provincial and Territorial Public Health Sites	9
Public Health Websites and Resources	. 10

Researcher Requirements

Researchers who propose to use in-person activities with research participants on campus and/or in community (off-campus) during the COVID-19 pandemic restrictions are required to seek Human Research Ethics Approval for the following (see instruction documents):

- 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) ¹
- 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)

UVic requirements (Human Research Ethics Board, Occupational Health, Safety and Environment, Biosafety Committee, etc.) <u>will be subject to change</u> to maintain alignment with provincial restrictions and ongoing changes to epidemiological modeling of infection rates.

As COVID-19 is a dynamic situation all resumption documents will continue to be updated.

If you do not see guidance on in-person activities specific to your study and require assistance, please contact the Human Research Ethics Office ethics@uvic.ca

Researchers who propose to use in-person activities during COVID-19 restrictions must be prepared for a sudden shut down in the event of new directives and advisories from the BC government, WorkSafe BC, public health entities, Indigenous nations as well as other regional, national or international directives or outbreaks that impact a specific study.

You must remain up-to-date on the public health reports and remain so for the duration of your study with participants. You must also be ready to adjust your ethics application based on new reports and to advise the Human Research Ethics Board of the specific COVID-19 situation in the locales where your inperson research is conducted.

Risks and Mitigations for Participant and Community Safety

[Publicly declared] emergencies may represent significant risks for research participants in ongoing research or in new research initiated as a result of the emergency. Potential participants who may not normally be considered vulnerable may become so by the very nature of the public emergencies, while those already vulnerable may become acutely so (Canadian Association of Research Ethics Boards, 2009).²

When proposing to use in-person activities with participants you must consider whether the activities could expose participants to elevated health risks and virus transmission within participants' households, families, local communities and beyond.

¹ Applies to paper-based studies and studies online in UVic-RAIS and the Provincial Research Ethics Platform

² SOP 501.003 REB Review During Publicly Declared Emergencies

Safety Practices

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)

Vulnerability

In particular, the following groups have been identified by public health as being vulnerable to COVID-19 or have a higher likelihood of severity: seniors and Elders, immune-compromised individuals, individuals with underlying health conditions (e.g., asthma, diabetes, cancer etc.), specific communities that could be considered vulnerable by the research and COVID-19 etc.

It is also necessary to consider the potential for increased psychological/emotional vulnerability of participants including attributes that may exacerbate mental health issues (e.g. OCD, anxiety, depression) because of the pandemic, including pandemic directives and preventative measures (e.g. isolation).

Also consider social attributes that put individuals at greater risk of exposure, of obtaining knowledge for taking preventive 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).

Participant Anonymity and Confidentiality for COVID-19 Exposure and Contact Tracing

Contact tracing is the process of identifying, assessing, managing and communicating with people who have been exposed to COVID-19 to prevent onward transmission. When systematically applied, contact tracing will break the chain of transmission and is considered an essential public health tool to control the virus.

From Island Health: https://www.islandhealth.ca/health-alerts/health-alerts/novel-coronavirus-covid-19

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

In the event that a research participant or member of your research team has tested positive for COVID-19 or are showing <u>symptoms</u> it may be necessary to follow local health directives to enable contract 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 in 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 stated in 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.

Research Team Safety and Communications with Research Team Members

In the event that a member of your research team has tested positive for COVID-19 or are showing symptoms it may be necessary to follow local health directives to enable contract tracing as this may be required in certain jurisdictions.

From Island Health: https://www.islandhealth.ca/health-alerts/health-alerts/novel-coronavirus-covid-19

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

Distribute your Human Research Ethics Approved Study for in-person research and UVic Safe Research Plan (if applicable) to your research team and ensure 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 Human Research Ethics Board of any required changes, protocol deviations, etc.

Campus Classrooms, Offices and Libraries

During COVID-19 restrictions campus activities, including research, falls under the purview of UVic Occupational Health, Safety and Environment (OHSE) and is subject to BC public health directives.

Access to classrooms and buildings on campus may be limited or not accessible during the resumption period of in-person research. Researchers proposing to use a classroom for in-person research with participants (e.g., conducting interviews or focus groups with participants) should request a room via non-academic room bookings, and follow instructions to apply for a campus Safe Work Plan to Occupational Health, Safety and Environment (OHSE).

Faculty proposing to use their own personal offices for in-person research activities with participants should also contact OHSE for guidance.

The use of library spaces (e.g., library rooms) may also be limited. Please check the libraries website. Use of library space also falls under UVic OHSE, and the campus Safe Work Plan.

Collection of Biological Samples

The safe collection of participants' biological samples such as saliva, sweat, urine, blood etc. are under the mandate of the UVic Biosafety Committee (Occupational Health, Safety and Environment).

Changes to the location, procedures and types of sample collection must be approved first by the Biosafety Committee and the updated Biosafety Registration document attached to the research ethics application. Please contact Biosafety if you have questions.

COVID-19 safety procedures such as physical distancing and disinfection measures may limit or prevent the collection of biological samples particularly in non-COVID-19 studies, general studies and those that do not fall under standard of care. Researchers proposing to resume or begin the collection of biological samples in non-clinical settings should consult with the Biosafety Committee and faculty at UVic or other institutions on best practices.

Course-based Research and Experiential Learning in Courses

Instructors with a course-based research ethics approval and those who apply for course-based approval are subject to the Human Research Ethics Instructions for On-campus Research and/or Community Research when the course assignment(s) for their students involves in-person research activities.

Instructors shall assess whether the specific and potential pedagogical benefits to be gained by students during in-person research outweigh the risks and additional responsibilities that they and their students are required to follow. Instructors must vet individual students' activities and ensure that students' course-based consent forms have been updated with the required COVID-19 information as set out in the On-campus Instructions and/or Community Research Instructions.

Students could still gain interview skills conducting remote interviews on UVic Zoom rather than gaining access to an organization to conduct in-person interviews.

When the assignment involves students conducting on-campus in-person activities with research participants (e.g., in-person interviews with or observations of UVic faculty, staff or students who are not attending the course) instructors must check with Occupational Health, Safety and Environment to see whether a campus Safe Work Plan is required.

COVID -19 Clinical and Public Health Studies to Alleviate the Pandemic

In-person clinical or public health research designed to alleviate the pandemic should, when possible, be conducted in collaboration with health professionals or community health organizations/agencies when researchers themselves are non-health professionals as access to patient participants or clinics may be limited or temporarily closed during the pandemic. It is imperative that partnering organizations/health clinics are able and willing to support COVID-19 health and safety protocols at the research sites/locations.

When a COVID-19 clinical or health study designed to alleviate the pandemic involves in-person research activities the Human Research Ethics Board reserves the right to review the application according to an "above minimal risk level" and in accordance with procedures set out for Research Ethics BC Harmonized Review (if applicable).

Please contact the Human Research Ethics Office about <u>Provincial Harmonized Ethics Review on the Provincial Research Ethics Platform</u> if a proposed study involves BC Health authority locations/clinics and/or team members.

Each health authority or clinic may have different restrictions on research and operations at this time. Please contact the Human Research Ethics Office if you have questions ethics@uvic.ca

Engagement with Indigenous, First Nations, Métis and Inuit Peoples (New and Ongoing Studies)

When establishing new partnerships, engagement and research relationships during COVID-19 restrictions researchers must seek direction from the Indigenous community on what is expected and what the engagement procedures entail.

When re-confirming ongoing partnerships, engagement and relationships it is vital to continue to learn what is expected from the community, seek their direction, and whether communities require changes to the research.

Researchers are required to continue to exercise their appropriate due diligence and take the time to find out what/how to step forward together with the community.

Whether the engagement is new or ongoing, researchers will or may need to learn about specific community protocols via remote forms of communication (e.g. email; phone; text; online communication platforms).

Many remote and Indigenous communities also require that outsiders undergo self-isolation before engaging with the community members. Researchers should ensure that they have the resources to abide by community requirements.

Equipment and Devices for In-person Research

The use of equipment or devices for in-person research attached to, used on or by participants will be evaluated by the Human Research Ethics Board on a **case by case basis** by assessing the study's risk profile - research ethics risks <u>and</u> COVID-19 health risk.

General equipment or devices used during in-person research activities with human participants refers to devices and machines that typically do not require special training to operate (e.g., computers, audio recorders, smart phones, fit bit, etc.).

During in-person research activities, it might, in some situations, be acceptable to involve the participant in the use of *general equipment* procedures (e.g., the researcher demonstrating first how the participant would self-attach part of the equipment to their body) when the participant has provided consent for this.

Specialized equipment or devices applies to equipment for which researchers and/or their research team members must be trained and follow standard protocols to operate safely (i.e., fMRI, EEG, EKG, ultrasound machines, etc.). Such equipment is typically used in research either for standard-of-care or outside standard-of-care (e.g., in non-hospital or non-clinical settings).

When using *specialized equipment*, depending on the age, ability or health of the participant, it may be acceptable to share some simple tasks that do not require training (e.g., participant fitting a cap on their own head, applying gel to their own scalp when COVID-19 safety procedures are also used such as use of

masks, gloves, disinfecting) and are within the equipment's safety requirements and insurance policy. The Research Ethics Board will review such situations on a case by case basis with the University's Risk Analyst. The Board reserves the right to reject proposed alterations to standardized equipment procedures on the grounds of safety and liability.

Researchers who use equipment (both general and/or specialized) in-person with research participants should describe COVID-19 prevention and safety procedures in the Human Research Ethics Application Form/Amendment Form (e.g., disinfection, gloves etc.). Include manufacturer's standards for disinfection for equipment (where applicable). Ensure that procedures are outlined clearly to participants within the Consent Form.

Non-UVic (external) Researchers

Non-UVic researchers who propose to come to campus to recruit UVic faculty, students or staff inperson and/or to conduct data collection in-person or in a UVic lab should contact UVic Occupational Health and Safety and Environment ohs@uvic.ca and the UVic Human Research Ethics Board. The two offices will communicate with each other and the external researcher. Note that there may be restrictions on research by non-UVic researchers on campus during the COVID-19 pandemic.

The Board and UVic Occupational Health, Safety and Environment reserve the right to restrict and suspend in-person research by non-UVic researchers on campus during the COVID-19 pandemic.

Research Involving Other Research Ethics Boards (including <u>Research Ethics</u> <u>BC</u> Harmonized studies) or Team members at Other Universities or Institutions

The Board recognizes that research ethics boards in other parts of the province or country may have different requirements from UVic for their researchers (faculty, students, staff, external researchers) during the "resumption phases of in-person research." Moreover, the rate and extent of the re-opening is likely to be geographically specific rather than a "one-size fits all" approach.

The Human Research Ethics office staff will assist supervisors, students and communicate with the research ethics boards of other institutions (university, hospital or health authority in BC, another province or outside of Canada) if applicable, should you require assistance.

Travel

The following are risk mitigations for in-person research involving travel³:

- 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.

-

³ from UBC Research Ethics

- 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.

Government of Canada Travel Advisory – includes global advisories https://travel.gc.ca/travelling/advisories

World Health Organization Dashboard https://covid19.who.int/

Provincial and Territorial Public Health Sites

Alberta

https://www.albertahealthservices.ca/topics/page16944.aspx

Saskatchewan

https://www.saskatchewan.ca/government/health-care-administration-and-provider-resources/treatment-procedures-and-guidelines/emerging-public-health-issues/2019-novel-coronavirus Manitoba

https://www.gov.mb.ca/covid19/index.html

Ontario

https://www.publichealthontario.ca/en/diseases-and-conditions/infectious-diseases/respiratory-diseases/novel-coronavirus

Quebec

https://www.guebec.ca/en/health/health-issues/a-z/2019-coronavirus/

Newfoundland and Labrador

https://www.gov.nl.ca/covid-19/

Nova Scotia

https://novascotia.ca/dhw/publichealth/

New Brunswick

https://www2.gnb.ca/content/gnb/en/departments/ocmoh/cdc/content/respiratory_diseases/coronavirus.html

Prince Edward Island

https://www.princeedwardisland.ca/en/topic/covid-19

Yukon Territory

https://yukon.ca/en/covid-19-information

Nunavut

https://www.gov.nu.ca/health/news/covid-19-department-health-services-update

Northwest Territories

https://www.gov.nt.ca/covid-19/

Public Health Websites and Resources

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)

World Health Organization Dashboard https://covid19.who.int/

BC First Nations Health Authority

https://www2.gov.bc.ca/gov/content/health/about-bc-s-health-care-system/partners/health-authorities/first-nations-health-authority