## Island Health Research Ethics Boards Guidance for Resuming In-Person Research After COVID-19 Restrictions

The Research Ethics & Compliance Office (RECO) and the Research Ethics Boards (REBs) at Island Health have updated their guidance in anticipation that authorization to resume in-person research of all types (e.g. health, socio-behavioural) will be fully implemented over the next few months.

Although the safety of research participants continues to be a factor in how research ethics applications are reviewed, the REBs have eased their requirements in alignment with updates issued by the British Columbia Public Health Officer (PHO) updated July 7th, 2021.

The REBs will be reviewing ethics applications taking into consideration the conditions in the research region including:

* Vaccination rates
* Rates of COVID-19 infection including variants
* Rates of hospitalizations due to COVID-19

While restrictions are easing, researchers should continue to consider ways they can reduce the risk of COVID-19 transmission within research teams and with participants. We are introducing Safe Research Guidelines and the Safe Research Plan template (August 2021) captured in an updated [form](https://redcap.viha.ca/redcap/surveys/?s=L8CPN7DNER) in REDCap. This replaces the *Request to Resume or Initiate a Research Study at Island Health* form.

The[**Request to Initiate or Resume In-Person Research at Island Health** form](https://redcap.viha.ca/redcap/surveys/?s=L8CPN7DNER) is only required for the initiation or resumption of in-person research. If you have completed the initial Request to Resume form, and there are no substantial changes to the current study related to in-person research, you do not need to complete the new form.

In instances where a Safe Research Plan is not required, researchers will still need to describe their safe research protocols for both new and resuming research. The REBs will not approve activities that do not adhere to the minimum standards imposed by the public health order for the community where the research is taking place.

To learn how your research may be affected, please find the sections below that most closely match your research scenario. If you are unsure of which description applies to your research, please contact REB staff. We continue to work remotely, but can be reached by [email](https://www.islandhealth.ca/research-capacity-building/research-ethics-approvals) under ‘Contacts’.

If your research takes place at a health authority site, specific policies and practices continue to apply. This includes considerations around operational approvals, if applicable. These are described in the most recent Research Notice. Where research is led by an academic institution or another health authority, their requirements will also apply when that research happens at or with Island Health. Guidance on this page is for Island Health researchers or those community research groups submitting to the Island Health REBs.

## PRINCIPLES FOR THE RESUMPTION OF IN-PERSON RESEARCH

* All in-person research that can be conducted safely may proceed.
* Researchers may not undertake research activities that will unnecessarily increase the risk to participants of contracting COVID-19.
* Researchers will provide details of their safe research plan to the degree required (see the scenarios below) based on the study’s risk status in the context of where in-person research is proposed and the nature of the research methods being employed.
* Please note that an amendment is required to resume all previously approved in-person research that has been on hold or to convert online studies to in-person research. Please see below for details.

## VACCINATION STATUS

The REBs endorse the [BC provincial COVID-19 vaccination program](https://immunizebc.ca/) and recommend that all researchers be vaccinated as a layer of protection for themselves and the participants with whom they interact. The relationship between researchers and participants is not the same as an employer-employee relationship; it is both legal and ethical. The ethics of trust articulated in the Tri-Council Policy Statement TCPS 2 (2018) – e.g. respect for persons, concern for welfare, and justice – applies to the researcher-participant relationship. Researchers also have a fiduciary duty to their participants, in much the same way that a physician has to their patients, which requires them to act in the best interests of participants.

While immunization is not mandatory, researchers do have a duty to disclose their vaccination status to research participants *if asked*. Further, the REBs may require that researchers disclose their vaccination status in their safety protocols and to their proposed participants in instances where:

* Research activities increase the number of in-person contacts experienced by participants;
* Research interactions need to take place over an extended period of time;
* There are challenges to mitigating the risk to participants.

In other instances, researchers who are not required to do so, may elect to disclose their vaccination status in their ethics application (as part of their safety protocols). Since research participants are not required to disclose their vaccination status, researchers should base their safety protocols on the premise that research participants *have not been vaccinated*.

## RESEARCH CONTEXT

The REBs will review ethics applications and related safety protocols in view of the specific research context and the risks entailed for both research participants and researchers. The following sections provide more detail about the information researchers will be required to provide and instructions for submitting new or resuming ethics applications. If you don’t find the information you are looking for, please [contact REB staff](https://www.islandhealth.ca/research-capacity-building/research-ethics-approvals) for a consultation.

Please be aware that, as the current situation is fluid, these interim policies may well change, and we will update you as necessary in future bulletins. Should you have any questions about these policies or other issues, please do not hesitate to contact E. Sarah Bennett, Manager, Research Ethics & Compliance | elizabeth.bennett@viha.ca.

### You are submitting a new application

All new ethics applications must be submitted through the [Research Services Portal](https://viha.researchservicesoffice.com/Romeo.Researcher/%28S%28l31midw5ykegdjtg3t5ipwcj%29%29/Login.aspx?ReturnUrl=%2fRomeo.Researcher%2fdefault.aspx) or [RISe](https://www.rise.ubc.ca/) (when multijurisdictional or harmonized) following usual procedures. Researchers should be aware of and follow the guidance at EACH SITE in which they plan to conduct research. For example, different hospitals may have different specific guidance as COVID-19 hospitalization rates may vary, etc. In general, the guidance should be similar. If submitting an application using RISe, please be mindful of this when describing how the study will be conducted at different sites.

Turnaround times for ethical review have returned to pre-COVID levels and, unless requested to do so, *the REBs are no longer prioritizing COVID-19 related research*. Turnaround time for minimal risk applications is 4-6 weeks and for full board applications is around 6-8 weeks (depending on researcher response times). [Full board meeting dates and deadlines through 2022](https://www.islandhealth.ca/research-capacity-building/research-ethics-review-boards) are listed online.

For specific details that apply to your research program, please review the requirements below.

#### You are conducting **new in-person research at an Island Health facility or site**

This guidance applies if you are conducting your research in a regulated facility or site under Island Health’s jurisdiction where COVID-19 safety protocols are in place:

* Follow the facility and/or institutional requirements.
* Ensure that your ethics application specifies the locations where your research will be conducted.
	+ Research Services Portal: Where applicable
	+ RISe: 4.2
* Institutions and Sites for Study:
	+ Research Services Portal: Where applicable
	+ RISe: Outline in Box 5.6 or 5.7 which safe research protocols you are following and confirm that a COVID health check will be used for all participants at the start of each interaction.
* Confirm that the Notice of COVID-related Risk will be included in the consent form package.
	+ Research Services Portal: 8.3
	+ RISe: Box 6.6
* For research being conducted outside Island Health facilities, attach any relevant safety protocol, if available:
	+ Research Services Portal: Attachments
	+ RISe: Box 9.7 (Behavioural Form) or 9.8 (Clinical Form)

#### You are conducting **new in-person research in a public setting that is at a non-Island Health facility or site** but within Canada

This guidance applies if you are conducting research that involves meeting participants in locations where safety protocols are unknown, such as a café, participant’s home or office.

* Ensure that your ethics application specifies the locations where your research will be conducted
	+ Research Services Portal: Where applicable
	+ RISe: 4.2
* Provide details of your safe research protocols and include a note that a COVID-19 health check will be used for all participants at the start of each interaction. You may alternatively use the Safe In-Person Research Plan Template to describe your safe research protocols and attach when you submit.
	+ Research Services Portal: 8.3
	+ RISe: In Box 5.6 and include the Safe Research Plan Template in Box 9.7 (Behavioural Form) 9.7 or 9.8 (Clinical Form), if applicable
* Confirm that the Notice of COVID-19 related Risk will be included in the consent form package.
	+ Research Services Portal: 8.3
	+ RISe: 6.6.

### Resuming Previously Approved or On-Hold Research

1. All researchers intending to resume in-person research will need to submit an amendment.
2. Researchers will need to conduct a COVID-19 health check with participants before each interaction.
3. Researchers will need to provide the Notice of COVID-19 related Risk to invitees/participants.
4. All research conducted outside of Island Health sites will need to include a Safe Research Plan. The REBs will consider current circumstances in the non-local area where the research is being undertaken, so please ensure that your Plan includes as much detail as possible about current public health directives, vaccination rates, rates of COVID-19 infection, and rates of hospitalizations due to COVID-19 in the non-local area where you will be conducting research.

For specific details that apply to your research scenario, please review the instructions below.

#### Your research received **conditional approval using in-person methods, and you are ready to apply for full approval**

If you received conditional approval from another BC REB via the harmonized process in RISe, for your research during the period of COVID-19 restrictions - and your study is in a Provisos Pending state on RISe - please ensure your application is up to date. Follow the instructions provided in the provisos issued before you resubmit for approval. Please feel free to contact the REB office if you have any questions about beginning your research.

#### **You received approval pre-COVID for in-person research but it has been on hold since the implementation of COVID-19 restrictions**

If you are conducting research at an **Island Health facility or site or in an institutional setting** (regulated facility such as a school or community centre):

* Follow the facility requirements.
* Ensure that your ethics application specifies the locations where your research will be conducted
	+ Research Services Portal: 3.2, Other Sites
	+ RISe: 4.2
* Explain clearly the changes:
	+ Research Services Portal: In Amendment Application, Section 1.8, Describe what has changed.
	+ RISe: Add a dated sub-heading at the bottom of any boxes that need to be amended, e.g. “July 2021 resumption of research amendment.” Do not overwrite previously approved content in the ethics application.
* Include a note that indicates which safe research protocols you are following and confirm that a COVID-19 health check will be used for all participants at the start of each interaction.
	+ Research Services Portal: Amendment Application, Attach with documentation
	+ RISe: 5.6.
* Confirm that the Notice of COVID-19 related Risk will be included in the consent form package.
	+ Research Services Portal: Amendment Application, Sections 1.14 and 1.15
	+ RISe: 6.6.
* For research being conducted Island Health facilities or sites, attach the facility’s safety protocol, if available.
	+ Research Services Portal: Attachments
	+ RISe: Box 9.7 (Behavioural Form) 9.7 or 9.8 (Clinical Form)

If you are conducting research in a **non-regulated setting, off-campus but within Canada** (e.g. café, participant home or office):

* Ensure that your ethics application specifies the locations where your research will be conducted
	+ Research Services Portal: 3.2
	+ RISe: 4.2
* Provide details of your safe research protocols and attach when you submit.
	+ Research Services Portal: 8.3
	+ RISe: In Box 5.6 or complete a Safe Research Plan and attach to Box 9.7. Add a dated sub-heading at the bottom of Box 5.6, e.g. “July 2021 resumption of research amendment” and describe any changes to your methods since pre-COVID approval. Do not overwrite previously approved content describing your research procedures.
* Include a note that a COVID health check will be used for all participants at the start of each interaction.
* Confirm that the Notice of COVID-19 related Risk will be included in the consent form package.
	+ Research Services Portal: 8.3
	+ RISe: 6.6

If you are conducting research outside Canada under Island Health jurisdiction or auspices:

Contact REB staff if your research falls into this category. Complete a Safe Research Plan and attach to Box 9.7 in RISe or with study documents in the Research Services Portal. All research conducted outside Canada of Island Health sites will need to include a Safe Research Plan. The REBs will consider current circumstances in the region in the non-local area where the research is being undertaken, so please ensure that your Plan includes as much detail as possible about current public health directives, vaccination rates, rates of COVID-19 infection, and rates of hospitalizations due to COVID-19 in the region(s)/non-local area where you will be conducting research.

#### **You converted your previously approved in-person methods to online in response to COVID-19 and want to resume in-person research**

If you are conducting research **on a campus or in an institutional setting** (regulated facility such as a clinic or long-term care facility):

* If your protocol was revised to include an addendum, and you will be reverting back to the original, please state this in the amendment application.
	+ Research Services Portal: Amendment Application, Section 1.8, Describe what has changed.
	+ RISe: Add a dated sub-heading at the bottom of any application boxes that need to be amended, e.g. “July 2021 resumption of research amendment.” Do not overwrite previously approved content in the ethics application.
* Follow the facility requirements. When you submit your PAA, ensure that your ethics application specifies the locations where your research will be conducted
	+ Research Services Portal: 3.2, Other Sites
	+ RISe: in Section 4.2, Institutions and Sites for Study.
* Indicate which safe research protocols you are following and include a note that a COVID-19 health check will be used for all participants at the start of each interaction.
	+ Research Services Portal: Include with Amendment Attachments
	+ RISe: Box 5.6
* Confirm that the Notice of COVID-19 related Risk will be included in the consent form package.
	+ Research Services Portal: 8.3
	+ RISe: Box 6.6
* For research being conducted outside Island Health facilities or sites (e.g. on school property), attach the facility’s safety protocol if available
	+ Research Services Portal: Include with Attachments
	+ RISe: to Box 9.7

**If you are conducting research in a non-regulated setting, off campus but within Canada (e.g. café, participant’s home or office):**

Add a dated sub-heading at the bottom of any boxes that need to be amended, e.g. “July 2021 resumption of research amendment.” Do not overwrite previously approved content in the ethics application.

In Box 5.6 provide details of your safe research protocols and include a note that a COVID health check will be used for all participants at the start of each interaction. You may alternatively use the Safe Research Plan Template to describe your safe research protocols and attach to Box 9.7.

Confirm in Box 6.6 that the Notice of COVID-related risk will be included in the consent form package.

#### If you are conducting **research outside Canada**:

Contact REB staff if your research falls into this category. Complete a Safe Research Plan and attach to Box 9.7 in RISe or with study documents in the Research Services Portal. All research conducted outside Canada of Island Health sites will need to include a Safe Research Plan. The REBs will consider current circumstances in the region in the non-local area where the research is being undertaken, so please ensure that your Plan includes as much detail as possible about current public health directives, vaccination rates, rates of COVID-19 infection, and rates of hospitalizations due to COVID-19 in the region(s)/non-local area where you will be conducting research.

#### **Your research received full approval using online-only methods and you want to change to (or add) in-person methods**

If you are conducting research **on a campus or in an institutional setting** (regulated facility such as a clinic or long-term care facility):

* Create an Amendment
* Add a dated sub-heading at the bottom of any application boxes to be amended, e.g. “July 2021 resumption of research amendment.” Do not overwrite previously approved content in the ethics application
* If changes are needed to documents attached to page 9 in RISe, or with Attachments in the Research Services Portal. Do not remove previous versions that were put into use. Add new versions of documents using track changes to make edits.
* Follow the facility requirements.
* Ensure that your amendment specifies the locations where your research will be conducted:
	+ Research Services Portal: 3.2, Other Sites
	+ RISe: in Section 4.2, Institutions and Sites for Study.
* Include a note that indicates which safe research protocols you are following and confirm that a COVID-19 health check will be used for all participants at the start of each interaction.
	+ Research Services Portal: Amendment Application, Attach with documentation
	+ RISe: 5.6.
* Confirm that the Notice of COVID-19 related Risk will be included in the consent form package.
	+ Research Services Portal: Amendment Application, Sections 1.14 and 1.15
	+ RISe: 6.6.
* For research being conducted Island Health facilities or sites, attach the facility’s safety protocol, if available.
	+ Research Services Portal: Attachments
	+ RISe: 9.7 or 9.8

If you are conducting research **in a non-regulated setting that is off campus but within Canada**:

This guidance applies if you are conducting research that involves meeting participants (in-person) in locations where safety protocols are unknown, such as a café, participant’s home or office.

* Create an Amendment
* Add a dated sub-heading at the bottom of any application boxes to be amended, e.g. “July 2021 resumption of research amendment.” Do not overwrite previously approved content in the ethics application
* If changes are needed to documents attached to page 9 in RISe, or with Attachments in the Research Services Portal. Do not remove previous versions that were put into use. Add new versions of documents using track changes to make edits.
* Follow the facility requirements.
* Ensure that your amendment specifies the locations where your research will be conducted:
	+ Research Services Portal: 3.2, Other Sites
	+ RISe: in Section 4.2, Institutions and Sites for Study.
* Include a note that indicates which safe research protocols you are following and confirm that a COVID-19 health check will be used for all participants at the start of each interaction.
	+ Research Services Portal: Amendment Application, Attach with documentation
	+ RISe: 5.6.
* Confirm that the Notice of COVID-19 related Risk will be included in the consent form package.
	+ Research Services Portal: Amendment Application, Sections 1.14 and 1.15
	+ RISe: 6.6.
* For research being conducted Island Health facilities or sites, attach the facility’s safety protocol, if available.
	+ Research Services Portal: Attachments
	+ RISe: 9.7 or 9.8

If you are conducting in-person research **outside Canada**:

#### Contact REB staff if your research falls into this category. Complete a Safe Research Plan and attach to Box 9.7 in RISe or with study documents in the Research Services Portal. All research conducted outside Canada of Island Health sites will need to include a Safe Research Plan. The REBs will consider current circumstances in the region in the non-local area where the research is being undertaken, so please ensure that your Plan includes as much detail as possible about current public health directives, vaccination rates, rates of COVID-19 infection, and rates of hospitalizations due to COVID-19 in the region(s)/s non-local area where you will be conducting research.

#### **You received full approval for in-person research with a Safe Research Plan and you want to relax your safety protocols**

* Create an Amendment
* Add a dated sub-heading at the bottom of any application boxes to be amended, e.g. “July 2021 resumption of research amendment.” Do not overwrite previously approved content in the ethics application
* If changes are needed to documents attached to page 9 in RISe, or with Attachments in the Research Services Portal. Do not remove previous versions that were put into use. Add new versions of documents using track changes to make edits.
* Follow the facility requirements.
* Ensure that your amendment specifies the locations where your research will be conducted:
	+ Research Services Portal: 3.2, Other Sites
	+ RISe: in Section 4.2, Institutions and Sites for Study.
* Include a note that indicates which safe research protocols you are following and confirm that a COVID-19 health check will be used for all participants at the start of each interaction.
	+ Research Services Portal: Amendment Application, Attach with documentation
	+ RISe: 5.6.
* Confirm that the Notice of COVID-19 related Risk will be included in the consent form package.
	+ Research Services Portal: Amendment Application, Sections 1.14 and 1.15
	+ RISe: 6.6.
* For research being conducted Island Health facilities or sites, attach the facility’s safety protocol, if available.
	+ Research Services Portal: Attachments
	+ RISe: 9.7 or 9.8

### You are beginning or resuming research in-community\* (includes rural and Indigenous research)

\*“In community” in this context refers to sustained in-person engagement with research populations over a period of time, beginning prior to the onset of formal data collection. In all cases, the REBs will be looking for demonstrated community support for the researchers being present and carrying out in-person research activity.

#### **Research in non-Indigenous communities**

If you are conducting research within Canada:

* Allowed at the discretion of the community
* Submit a Safe Research Plan co-created with the community
	+ Research Services Portal: Attachments
	+ RISe: Box 9.7.
* Include a note that a COVID health check will be used for all participants at the start of each interaction.
	+ Research Services Portal: 8.3
	+ RISe: Box 5.6

If you are conducting research outside Canada:

#### Allowed at the discretion of the community.

#### Contact REB staff if your research falls into this category. Complete a Safe Research Plan and attach to Box 9.7 in RISe or with study documents in the Research Services Portal. All research conducted outside Canada of Island Health sites will need to include a Safe Research Plan. The REBs will consider current circumstances in the region in the non-local area where the research is being undertaken, so please ensure that your Plan includes as much detail as possible about current public health directives, vaccination rates, rates of COVID-19 infection, and rates of hospitalizations due to COVID-19 in the region/s non-local area where you will be conducting research.

#### **Research in Indigenous communities**

The guidance provided here was drafted for the Canadian context. However, there may be relevant content for research conducted in other Indigenous communities. If you are conducting research in communities outside Canada and are needing assistance, please feel free to contact the Research Ethics & Compliance office.

You are advised to review the guidance, Culturally Safe and Trauma-Informed Practices for Researchers during COVID-19 before finalizing your research logistics. You should also review Section 4 “Research Involving Indigenous Communities” in the Safe Research Guidelines.

*Research will be reviewed once there is agreement from the community*, as demonstrated through an attached research agreement, MOU or other proof of approval. *If you have a previously existing MOU with a community, this agreement should be re-affirmed*.

* Attach your Safe Research Plan co-created with the community
* Include a note that a COVID-19 health check will be used for all participants at the start of each interaction.
	+ Research Services Portal: 8.3
	+ RISe: Box 5.6
* Confirm that the Notice of COVID-related risk will be included in the consent form package.
	+ Research Services Portal: 8.3
	+ RISe: Box 6.6

### You are a student conducting research outside Canada

Refer to your home institution’s guidance around travel advisories and any requirements around travel in place at that level.

### Forms and Resources

#### [Request to Initiate or Resume In-Person Research at Island Health](https://redcap.viha.ca/redcap/surveys/?s=L8CPN7DNER)

Safe In-Person Research Guidelines

Safe In-Person Research Plan Template

#### **COVID-19 Health Check** ⎢ Researchers are required to have participants and research team members complete a questionnaire at the onset of each in-person engagement. We provide a link to the latest [BC COVID-19 Self-Assessment Tool](https://bc.thrive.health/covid19/en) (multiple languages are available from this link). This tool or a similar set of questions must be used. The questionnaire does not need to be attached to the ethics application, but confirmation of its use needs to be provided in the application in either Research Services Portal or RISe. See the scenarios described above for instructions.

#### Notice of COVID-Related Risks During Research

#### [Culturally Safe and Trauma-Informed Practices for Researchers during COVID-19](https://www.bcahsn.ca/sites/default/files/2021-06/Culturally%20Safe%20and%20Trauma-Informed%20Practices%20for%20Researchers%20during%20COVID-19.pdf)

#### [Zoom Guidance for Research](https://www.islandhealth.ca/sites/default/files/research/documents/guidance-research-using-zoom-video-teleconferencing-options.pdf)

### Detailed Documentation Guidelines for COVID-Related Research

The following applies both to new studies and amendments to previously approved ethics applications. In order to mitigate risks associated with the inclusion of COVID-related topics, please follow this guidance.

**Recruitment materials (including ads, posters, letters of invitation, information sheets)**

Clearly state that the research involves discussion/consideration of topics related to the COVID-19 pandemic.

If questions about the pandemic are not optional, make this clear in recruitment materials so invitees can choose to opt out.

**Consent forms/scripts**

Clearly disclose that the researcher will be asking COVID-related questions and provide the research justification in lay terms for including the topic.

Provide examples of COVID-related questions you will be asking.

Indicate whether COVID-related questions can be skipped. If answering the COVID-related questions is a condition of eligibility, (i.e. if not answering would disqualify a participant), make this clear so invitees don't waste their time.

If COVID-related questions are being added to a study in progress, all participants still active in the study will need to be reconsented. This could be done either through a supplementary script or email explaining the nature of the additions and options available to them (e.g. withdraw from further participation without penalty, skip the COVID-related questions, proceed to answer all questions). Attach the consent renewal materials to Box 9.2.

If COVID-related samples are being collected as part of the research, explain:

1. If it is optional;
2. Why it is being collected, and;
3. Who the information is being shared with.

**Questionnaires/surveys**

Provide a warning at the point where COVID-related questions begin, e.g. “The next 5 questions are asking about your experience with the COVID-19 pandemic. You can skip these questions if you prefer not to answer them. “

Ensure that the survey tool allows participants to skip questions, either by providing a “prefer not to answer” response or by allowing users to bypass the question set. E.g. “I would like to skip this section.” The BREB prefers that both options are provided, since some people may not even want to read the questions or may change their mind partway through.

**Interview script**

During the interview introductions, explain how you will handle the COVID-19 related questions and what options are available to participants.

If answering questions about COVID are essential to participating in the research, we recommend that you seek verbal confirmation from the participant at the beginning of the interview to ensure that they understand, but also remind them that they can decide at any point to discontinue the interview. E.g. “I am asking for your agreement to answer questions about the COVID-19 pandemic during this interview. But even if you say “yes” now, you can still change your mind later.”

If the questions are optional, explain how participants can signal to you that they do not want to answer COVID-related questions.

**Focus-group script**

Because individual participants will have less control over a focus group discussion than in a one-to-one interview scenario, special care should be taken. Before the discussion begins:

Remind participants that COVID-19 will be discussed.

Include a warning that participants may find the topic upsetting and they should feel free to leave at any time.

Advise participants that information disclosed in the session should not be shared outside the group, but remind participants that the researcher cannot guarantee confidentiality.

**List of support services & resources**

Attach a list of resources to your application and ensure the services are continuing to function during the pandemic restrictions.

Provide the list of resources to participants at the outset of their engagement and how it will be done.