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