COVID-19 Q&A

1. Can research with Indigenous peoples and/or communities continue?
   ✓ Researchers working with Indigenous peoples and/or communities should stop research/data gathering and determine when such work may continue only after you have consulted with the community in question. It is best practice to consult with the communities to determine whether they wish for you to continue with the research collaboration.

2. Can Non-Hospital Based Researchers still conduct their work if it involves in-person methodology?
   ✓ Given the public health emergency related to COVID-19 we are requesting that researchers proposing in-person contact and/or in-person research with communities do not initiate in-person data collection until this public health emergency is over. Modifications should be made to eliminate in-person (e.g., conduct interviews, focus groups remotely, on-line surveys, etc.) if possible.
   ✓ If the research study is providing an essential treatment option that is absolutely necessary for the welfare of the participant(s) a request for exemption will be required. Exemption requests need to be vetted by Jennifer Couture, Manager, Research Ethics Compliance, (Jennifer.couture@queensu.ca) to bring forward to the appropriate REB Chair for consideration.
   ✓ New ethics applications that do propose in-person contact will only be granted a conditional ethics clearance by GREB/HSREB. Conditional ethics clearance means your study has received ethics clearance but you do not have permission to start in-person data collection until COVID-19 research restrictions are removed and you receive an updated ethics clearance letter. Other aspects of the research not involving in-person contact may start once conditional clearance is issued (e.g., secondary data review, remote survey).
   ✓ Amendments to ongoing research studies should clearly outline all strategies being implemented to eliminate face-to-face interactions (i.e., virtually or through other means).
      — Please see “What do I need to do if I need to change my current procedures/protocol due to COVID-19?” below for additional guidance.

As greater clarification on risks of COVID-19 spread and risk of infection is provided by Queen’s University and our Public Health partners, these restrictions will be re-assessed. Please visit https://www.queensu.ca/vpr/covid-19 for the most up to date information on the COVID-19 Outbreak and its Impact on Queen's University Research

Some Considerations where face-to-face interactions are deemed absolutely necessary:
   a) Are any modifications to the protocol necessary to aide in social distancing? If yes, what steps can be taken to minimize risks to participants, researchers, research staff, trainees and the institution (e.g., telephone, virtual technology, mail).
   b) If meeting with participants or other researchers in-person are necessary, they should be contacted ahead of time to ensure that they are not showing any clinical symptoms of COVID-19. If they are, the appointment should be re-scheduled when signs have resolved.

3. Can Hospital-Based Researchers still bring participants to Queen’s University Campus or within the Hospitals for research purposes?
   ✓ Effective March 16, 2020, unless the research study is providing an essential treatment option with a limited enrollment option, enrollment of new research participants into research studies occurring at Kingston Health Sciences Centre (KHSC) (KGH and HDH sites) and Providence Care
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Centre (PCC) (including Ongwanada) should be stopped until further notice. Any special exemption requests to the above need to be vetted to Jennifer Couture (jennifer.couture@queensu.ca) to bring forward to the HSREB Chair for consideration prior to researchers completing a HSREB full ethics submission in TRAQ.

Access to the W.J. Henderson Centre for Patient-Oriented Research on Connell 4 of the KGH site of KHSC will be restricted to ongoing research activities. Researchers and research staff must use their Hospital ID to access the Centre. Please see Question 9 below for more details about research follow-up visits occurring at KHSC/PCC.

Queries specifically related to KHSC-based research should be sent to Veronica Harris-McAllister (Veronica.Harris-McAllister@kingstonhsc.ca), copying Steven Smith (Steve.Smith@kingstonhsc.ca) while those related to research at PCC should be directed to Alison Philpot (philpota@providencecare.ca), copying Claudio Soares (Claudio.Soares@kingstonhsc.ca).

4. Can we continue to enroll participants that are already in-patients in a restricted participant population (e.g., ICU, dementia, ER) or if conducting research related to Standard of Care at KHSC/PCC?

- Yes, enrolment for certain types of inpatient research may continue if it is in the best interest of the participant(s), if it provides an essential treatment option or it directly relates to providing Standard of Care. You should still be compliant with applicable social distancing measures. If you are unclear if your study should continue to enroll participants please email jennifer.couture@queensu.ca.
- In-person contact should be minimized for all on-going research. Please view “Some Considerations” above for more information.

5. What do I need to do if I would like to start a new study related to COVID-19 and I need to get my ethics review expedited?

- Complete and submit the appropriate ethics application form in TRAQ (FAQ re: registering in TRAQ posted on the GREB/HSREB websites). Ensure you have reviewed the GREB/HSREB LOI/CF Checklist (posted on the GREB/HSREB websites) as applicable.
- Once the application has been submitted through the TRAQ website, forward the notification of submission from TRAQ via email to jennifer.couture@queensu.ca.
- For hospital-based research at KHSC/PCC and/or for contract/agreement review, you will also be required to submit a TRAQ DSS FORM application. This should be submitted at the same time as the ethics application to streamline the review process.

6. What do I need to do if I need to change my current procedures/protocol due to COVID-19?

- Any changes should be implemented to eliminate immediate hazards to participants prior to review by the appropriate REB. If any changes are implemented, submit for REB review as soon as possible. For GREB, submit this information using the GREB Amendment Event Form in TRAQ. For HSREB, submit any planned and/or previously implemented changes using the HSREB Amendment Event Form. For CTO/OCREB submit through CTO Stream. Additionally, for changes implemented prior to HSREB review, submit a HSREB Protocol Deviation Event Form. All event forms can be found through the ‘events’ link beside the file number when you log into TRAQ.

7. Am I able to remove my research files from KHSC/PCC and store them in a secure location in my home due to COVID-19? I may have participants contact me and I may need this information to answer questions.
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If you plan to store any research files at home they must be de-identified as outlined in the ethics application. Keep in mind the following:

- Take all reasonable precautions to protect privacy. Protecting privacy should be a priority (e.g., secure storage in a separate room that can be locked, locking files in the trunk of a car during transport rather than the backseat where they are visible).
- Files should only be kept off-site for as long as necessary.
- Document in a log all study-related documents that are leaving KHSC/PCC, which includes what research files were taken off-site, participant ID# of files taken, date of removal of research files, date of return of research files, and who took the files (study staff ID).
- Submit an Amendment Event Form to the appropriate REB outlining the new storage procedures and location.

8. Is the recruitment of participants to complete on-line surveys still permissible if being conducted by hospital-based researcher (KHSC/PCC) since this does not involve entry to KHSC/PCC?

- Yes, recruitment to on-line surveys is still permissible for hospital-based research. All in-person contact for research purposes should be minimized. Please view “Some Considerations” above for more information.

9. If we have to implement new procedures due to COVID-19 mandated by the health care system for on-going research do I need to submit an Amendment Event Form in TRAQ?

- As per the new FDA Guidance titled, ‘FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic’ we are following the same guidelines:

  “COVID-19 screening procedures that may be mandated by the health care system in which a clinical trial is being conducted do not need to be reported as an amendment to the protocol even if done during clinical study visits unless the sponsor is incorporating the data collected as part of a new research objective.”

10. Should I be conducting follow up visits with my research participants?

- Follow up should continue only as it relates to the best interest of the participant(s).
- In-person contact should be minimized, if any visits can be done virtually or by telephone an amendment form should be updated to outline this change to the appropriate REB. Review “What do I need to do if I need to change my current procedures/protocol due to COVID-19?” above for additional guidance.

- If research participants are required to enter KHSC/PCC for research follow-up visits, they should be contacted ahead of time to ensure that they meet the COVID-19 screening criteria for allowing entry into KHSC/PCC. These criteria change regularly, so please ensure before the call that you have the most updated information on hand. If the participant is not able to pass the screening, the appointment should be rescheduled. Participants must enter the designated screening checkpoints before making their way into KHSC/PCC. Research staff should meet them upon entry and escort them to the designated location for research follow-ups. Expect delays coming in at screening. If participants do not pass screening at the checkpoints, they will not be allowed entry into KHSC/PCC. Please let participants know that they may only have a maximum of one (1) person accompanying them but are encouraged to come alone, if possible. Any individuals accompanying participants must pass screening to be allowed into KHSC/PCC.