**To All Researchers Undertaking Human Participant Research**

**Please find below the specific steps required for re-opening your clinical research at Kingston Health Sciences Centre (KHSC), Providence Care Hospital, or Queen’s University in the COVID-19 era.**

Three key steps:

1. Identify the clinical research that best fits your research program.

2. Review the SOP approved by IPAC shown below to ensure your program meets the requirements. Sign and submit to relevant contact below.

3. Complete the University research application form found at:

<https://www.queensu.ca/vpr/covid-19/research-facility-start-and-requests-site-access>.

For approval of applications based in the Faculty of Health Sciences and hospital sites, submit the signed and modified SOP, and completed research restart form to: Dr. Steven Smith (c/o Ms. Gladys Smith: gladys.smith@queensu.ca).

Be sure to identify the site of your research activities and specific factors, as outlined below, and any other factors that you believe may be relevant in this COVID-19 era.

**Step 1. Identify the clinical research that best fits your research program.**

Outlined below are the main research sites and types of research studies. They may differ in the relative ease of opening up in the context of the COVID-19 pandemic as each scenario has some unique factors that require consideration and specific comment in your application. (Note: patients that can be enrolled virtually can proceed with HREB approval and studies that have continued during COVID-19 will proceed as already approved).

i)  Clinical studies involving patients seen at the KHSC - HDH site outpatient center as part of their routine clinical care.

- How long is the contact, e.g., < 15 min?

- What PPE required?

- Is the non-research staff engagement prolonged?

- How many participants are anticipated per week?

ii)  Clinical studies that bring patients for research purposes into research space in the KHSC – KGH site or Providence Care Hospital (PCH)

- How many patients are involved?

- What is the plan for screening and logistics for moving through the hospital to the research space?

- Is there sufficient research space to accommodate the patients and staff to allow for COVID-19 guidelines of physical distancing etc.?

- What are the PPE requirements?

iii) Clinical studies involving patients for research purposes in the outpatient setting at the KHSC – HDH site.

- Does the patient’s requirement for screening prevent patients requiring clinical care from being seen due to the ceiling for numbers that can be screened each day?

- Additional factors as outlined in i) above. (Could they be seen at an alternate site: e.g., WJ Henderson Centre for Patient-Oriented Research on Connell 4, KHSC - KGH site)

iv) Research involving patients admitted to the emergency room or hospital inpatient setting.

* Need for PPE for patients and research staff?
* Is there increased exposure time for non-research staff?
* Is there increased risk for research staff?

v)  Hybrid of online enrolment and in person visit. This could apply to scenario 2 or 3. In person could be dropping off sample or picking up sample container, for example.

New studies will fall into one of the above scenarios. Existing studies within that scenario have relative priority, particularly if funding for current research staff is at risk.

**Step 2. Review this general SOP to ensure your program meets the standards**

**Standard Operating Procedure**

**Title:** Clinical Conduct Accommodations for COVID-19

**Contents:**

1. Introduction
2. Training and Reference Materials
3. Informed Consent
4. Study Planning Considerations
5. Telephone Pre-Screening Procedures
6. Study Visit Procedures
7. Use of Personal Protective Equipment
8. Sample Collection, Handling, and Processing
9. Additional Study-specific Details

**Resources:**

KSHC IPAC Resource: *Guide for Accessing PPE at KHSC Sites*

KHSC IPAC Resource: *Steps for Donning & Doffing Personal Protective Equipment*

KHSC IPAC Policy 2-05 Hand Hygiene

KHSC IPAC Policy 2-10 Routine Practices

KHSC IPAC Policy 2-25 Gloves Indications & Procedures

KHSC IPAC Policy 3-30 COVID-19

**1. INTRODUCTION**

As a response to the COVID-19 pandemic and in compliance with guidelines for local, provincial and federal authorities, several changes have been made to the clinical research procedures at Kingston Health Sciences Centre (KHSC) – KGH site *OR* Kingston Health Sciences Centre (KHSC) – HDH site *OR* Providence Care Hospital (PCH) *OR* Queen’s University.

Community safety must be balanced with the immediate benefits and long-term value of clinical studies. In order to continue clinical research, the document will discuss considerations and procedures customized for clinical research activities during the COVID-19 pandemic. Participant and staff safety are always the top priority. The PI and their research team will work with local regulatory bodies to conduct clinical research safely and effectively.

Due to the nature of the rapidly changing situation, recommended procedures and policies may change after the implementation of this SOP. In the event of major changes to the Infection Prevention and Control (IPAC) recommendations investigators will be notified of the changes and a response that they are being complied will be required within 24 hours.

**2. TRAINING AND REFERENCE MATERIALS**

All research team members must have completed the standard required training as required by the HREB (i.e., Good Clinical Practice (GCP) or Course on Research Ethics (CORE) training certificates for all team members interacting with participants or handling data sets. Research team members should also be conversant with the SOP documentation. If the study will be conducted in the WJ Henderson Centre for Patient-Oriented Research (WJHCPOR) team members should contact the KGHRI staff regarding specific training requirements. Additional education and training specific to ongoing studies and assignments, including relevant biosafety training, is require if deemed necessary by the PI. (See specific guidelines about PPE below under #6 below)

**3.** **INFORMED CONSENT**

Consent forms need to be amended to include acknowledgement of the remote possibility that a participant could come into contact with someone with COVID-19 during their research pathway and to allow for contact tracing. Specifically, consent forms need to be amended with the following statement:

“There is a remote possibility that during your research activities you could come into contact with someone with COVID-19. If this highly unlikely event were to occur, we are required by the Public Health Unit to retain on file your email address or phone number to share with them for contact tracing purposes”.

**4. STUDY PLANNING CONSIDERATIONS**

The first priority of the PI will always be the participant, staff and trainee safety, as well as the safety of others at KHSC-KGH *or* KHSC-HDH *or* PCH *or* Queen’s University. Before clinical research participant activities are initiated, the PI will determine the feasibility of the study activities as laid out in the proposal, and weigh the study timeline and long-term benefits with risk assessment. Where there are unique circumstances beyond the general IPAC guidelines, they will work with Kingston General Health Research Institute (KGHRI), KHSC IPAC, Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB), Queen’s University Environmental Health and Safety, and any study sponsors to create a plan that allows for effective and safe study conduct.

If possible, some study visits may be planned to occur over the phone or by email, i.e., “check-in” style visits to ensure study compliance or confirm that there are no adverse events or additional symptoms to report. Any study-specific adjustments beyond this SOP will be documented in a study-specific note to file and store with study documents.

**5. TELEPHONE PRE-SCREENING PROCEDURES**

After a human participant study has been approved by the regulatory bodies (if applicable), including the HSREB, recruitment will commence either in person or virtually. In addition to the standard screening questions required for study protocols, participants will be asked the current KHSC IPAC screening questions (<https://kingstonhsc.ca/patients-families-and-visitors/covid-19-information/screening-khsc>sps1).

**6. STUDY VISIT PROCEDURES**

Study visits will be planned in such a way as to emphasize participant, staff and trainee safety and make sure that all participants feel comfortable. An early part of the communication with participants will be to give them an overview of our policies and practices, and give them the opportunity to ask questions, so that they feel comfortable coming on-site for a study visit/follow-up.

Study-specific activities may require specific customizations to this plan, but the following principles will govern study visits:

* Maintain appropriate social distancing whenever possible.
* Maintain the highest standard of cleanliness, including regularly disinfecting high touch surfaces, cleaning exam/procedure/study rooms between each participant, and good hand hygiene. *See KHSC IPAC Policy 2-05 Hand Hygiene.*
* Follow KHSC IPAC policies, including the use of Personal Protective Equipment (PPE) and screening procedures. *See KHSC IPAC Policy 3-30 COVID-19* and *section below for additional details on use of PPE.*

Allowing for study-specific customizations, study visits occurring at the KHSC – KGH site will be conducted in the following manner:

1. Participants will receive a telephone call the day before their visit to ensure that they are not experiencing any symptoms. Any participants that do not feel well will have their visit cancelled or rescheduled.
2. All participants must enter the KHSC – KGH site through the main Kidd/Davies Entrance at 76 Stuart Street access the research study site. They will complete COVID-19 screening procedures at entrance of all the respective sites.
3. For participants attending for research purposes only, a research team member will meet the participant in the main lobby and guide them to the study location.
	1. For studies that that will occur in Connell 4 WJHCPOR at the KGH-site of KHSC: In groups of no more than four (4) participants, the staff member will lead them to the Connell elevators. This will minimize the potential of participants getting lost or wandering through hospital unnecessarily. The staff member will bring the participants to Connell 4 in an otherwise empty elevator (skipping elevators with other visitors or staff to ensure no more than four (4) people per elevator. If the group includes four participants plus the staff member, the staff member will take the stairs and instruct the participants to exit on Connell 4 and wait just outside of the elevator). The participants will enter WJHCPOR.
	2. For studies that will occur at other locations at the KHSC-KGH site or at KHSC-HDH site, PCH or Queen’s University: In groups of no more than four participants, a staff member will lead participants to the study location. Where necessary, the same elevator procedures as outline in 3a. will be followed.
4. For participants attending for research purposes only, the research site will be set up to limit participant access. Hallways and lobbies will be blocked off whenever possible and practical, and individual stations will be set up in exam rooms. Only designated bathrooms will be used. A designated room will be used for informed consent sessions. These sessions will be conducted with a maximum of four (4) participants whose chairs will be set up at an appropriate distance. Participant wait times will be minimized whenever possible to reduce potential exposure time and interaction with other participants.
5. Rooms will be disinfected between each participant. Additional high touch surfaces, including door handles and light switches, will be disinfected regularly.
6. If a participant does not pass onsite screening or are determined to be a potential risk (e.g., determined to have a fever when vital signs are collected), the participant will be asked to don appropriate PPE and will be immediately referred to a study physician for further examination or to attend the COVID-19 Assessment Centre.
7. During the study visit, there will be no other research projects booked in the main part of the WJHCPOR and/or in the immediate vicinity of the research area, as applicable.
8. For participants attending the clinic as part of routine clinical care, the study visit can occur within the clinical visit room, provided the extension of the clinic time does not disrupt patient flow (typically < 15 min).

**7. USE OF PERSONAL PROTECTIVE EQUIPMENT**

The PI will work with the study team members, and in consultation with KHSC IPAC guidelines, to determine appropriate PPE use for specific study activities. KHSC IPAC Resources PPE Section contains helpful tools, which may be consulted to determine the use of PPE for specific activities:

Although team members are experienced with the use of PPE, all staff should review the attached appendices, if relevant:

 *KHSC IPAC Resources Steps for Donning & Doffing Personal Protective Equipment*

 *KHSC IPAC Policy 2-10 Routine Practices*

 *KHSC IPAC Policy 2-25 Gloves Indications & Procedures*

 *KHSC IPAC Policy 2-30 Respirators, Masks, Eyewear: Indications & Procedures*

The PI and study team member should work with appropriate research site representatives to ensure sufficient supply of PPE, including gloves, masks, and disinfectant wipes. All steps outlined in KHSC IPAC *Resource Guide for Accessing PPE* [ at *KHSC Sites, PCH, Queen’s*] will be followed.

**8. SAMPLE COLLECTION, HANDLING, AND PROCESSING**

Biological samples collected during study visits are always handled by qualified team members with the highest regard for safety. Samples will be collected by study nurses and/or physicians as most appropriate. They will be handled, processed, and/or shipped by qualified team members. Samples may be sent to appropriate third party labs if required by study specific protocols.

**9. ADDITIONAL STUDY-SPECIFIC DETAILS**

Add details

**10. SIGNATURES**

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Name & Signature of Principal Investigator Steven Smith, Vice-Dean (Research), FHS

Date: Date: