**Faculty of Health Sciences**

**Request for New Human Participant Project Start Up Approval**

Completed and signed forms are to be submitted to the office of the FHS Vice-Dean of Research for Dr. Steven Smith’s review and approval. Email the request, along with a copy of the Ethics Clearance/Approval to both Dr. Smith and his assistant, Gladys Smith. Gladys.Smith@queensu.ca; Steven.Smith@queensu.ca

**Investigator Information:**

|  |  |
| --- | --- |
| Principal Investigator Name: |  |
| Department/School/Research Group: |  |
| Cell Phone # (for emergency contact): |  |
| Email address: |  |

**Project Information:** (Projects must have received full approval through TRAQ, and have been given a project or fund number for financial administration of the project before a request will be reviewed).

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| --- | --- |
| Project Name: |  |
| TRAQ DSS#: |  | Finance Project/Fund #: |  |
| Project Start Date:(as per letter of award) |  | Project End Date:(as per letter of award) |  |

**Human Participant Information:**

|  |  |  |
| --- | --- | --- |
| Does your project involve: | Data review only | Y or N |
|  | Clinical Recruitment | Y or N |
|  | Research Participant Recruitment (non clinical) | Y or N |
| Provide a brief summary of the study and participant involvement (e.g., experimental methods to be used and description of process if physical distancing cannot be maintained).  |
|  |
| **ATTACH a copy of your Ethics Clearance/Approval with your submission.**  |

**Locations/Buildings Being Used:** (Specify the building/site/department, room numbers which will be used, and the activity (e.g., Emerg Dept for “recruitment”, WJHCPOR “in-person interviews”,) where the research will be conducted.)

|  |  |  |
| --- | --- | --- |
| **Building/Site/Department** | **Room Number(s)** | **Activity** |
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If required, use the “Tab” button when in the last cell to add more rows to the above table.

The Faculty of Health Sciences’ Standard Operating Procedure for Human Participant Research (revised 17 July 2020) is attached to this form. PIs are required to review the document. In the process of reviewing the document and familiarizing yourself with the SOPs: 1) identify the clinical research that best fits the research project; 2) add additional relevant study-specific details in the next section; and 3) sign and submit to the FHS Research Office.

**Faculty of Health Sciences’ Standard Operating Procedure
for Human Participant Research
(revised 17 July 2020)**

**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.

1. Clinical studies involving patients seen at the KHSC-HDH site outpatient centre 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?
2. 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?

1. 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?)

1. 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?
1. Hybrid of online enrolment and in person visit. This could apply to scenario ii) or iii). In person could be dropping off sample or picking up sample container, for example.

New studies will fall into one of the above scenarios. Highlight the most relevant scenario above associated with your research project, and add specific details not specified on the previous form.

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**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:** (Links will download documents from Queen’s University Vice-Principal Research website)

[KSHC IPAC Resource: Guide for Accessing PPE at KHSC Sites](https://www.queensu.ca/vpr/sites/webpublish.queensu.ca.vprwww/files/files/COVID-19/Guide-for-accessing-PPE-at-KHSC-Sites_April%2020-2020_.pdf)

[KHSC IPAC Resource: Steps for Donning & Doffing Personal Protective Equipment](https://www.queensu.ca/vpr/sites/vprwww/files/uploaded_files/COVID-19/Steps-for-Donning-Doffing-PPE.pdf)

[KHSC IPAC Policy 2-05 Hand Hygiene](https://www.queensu.ca/vpr/sites/vprwww/files/uploaded_files/COVID-19/2-05%20Hand%20Hygiene%20Final%2020190131.pdf)

[KHSC IPAC Policy 2-10 Routine Practices](https://www.queensu.ca/vpr/sites/vprwww/files/uploaded_files/COVID-19/2-10-RoutinePracticesFinal-20190123.pdf)

[KHSC IPAC Policy 2-25 Gloves Indications & Procedures](https://www.queensu.ca/vpr/sites/vprwww/files/uploaded_files/COVID-19/2-25-GlovesIndicationsandProcedures-ICC-20181128.pdf)

[KHSC IPAC Policy 2-30 Respirators, Masks, Eyewear: Indications & Procedures](https://www.queensu.ca/vpr/sites/vprwww/files/uploaded_files/COVID-19/2-30-RespiratorsMasksEyewearIndications-Procedures-ICC20181128.pdf)

**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 *OR* -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 with 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 #7 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.”

If the Board of Record (BOR) is external to Queen’s (e.g., CTO, COG, etc.), please contact the BOR for any relevant language related to COVID-19 and ensure that it is included in the LOI/CF.

**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>).

**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*](https://www.queensu.ca/vpr/sites/vprwww/files/uploaded_files/COVID-19/2-05%20Hand%20Hygiene%20Final%2020190131.pdf)*.*
* Follow KHSC IPAC policies, including the use of Personal Protective Equipment (PPE) and screening procedures. *See* [*KHSC IPAC Policy 2-30 Respirators, Masks, Eyewear: Indications & Procedures*](https://www.queensu.ca/vpr/sites/vprwww/files/uploaded_files/COVID-19/2-30-RespiratorsMasksEyewearIndications-Procedures-ICC20181128.pdf)*,* and *section 7) below for additional details on use of PPE.*

Allowing for study-specific customizations, study visits occurring at the KHSC-KGH or KHSC-HDH sites 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. Participants entering the KHSC-KGH site must do so through the main Kidd/Davies Entrance at 76 Stuart Street to access the research study site. They will complete COVID-19 screening procedures at the entrance. *Please note that screening questions are continually being updated, which may impact the participant’s ability to enter the building so please be familiar with the most recent version.*
3. Participants entering the KHSC-HDH site must do so via the Brock Street Main Entrance to access the research study site. They will complete COVID-19 screening procedures at the entrance. *Please note that screening questions are continually being updated, which may impact the participant’s ability to enter the building so please be familiar with the most recent version.*
4. For participants attending for research purposes only, a research team member will meet the participant at the respective entrance listed above and guide them to the study location.
	1. For studies that that will occur in Connell 4 WJHCPOR at the KHSC-KGH site: 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 iv.a. will be followed.
5. 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.
6. Rooms will be disinfected between each participant. Additional high touch surfaces, including door handles and light switches, will be disinfected regularly.
7. 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 be instructed to attend the COVID-19 Assessment Centre.
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. The 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 linked resources and policies below, if relevant:

* [KHSC IPAC Resource: Steps for Donning & Doffing Personal Protective Equipment](https://www.queensu.ca/vpr/sites/vprwww/files/uploaded_files/COVID-19/Steps-for-Donning-Doffing-PPE.pdf)
* [KHSC IPAC Policy 2-10 Routine Practices](https://www.queensu.ca/vpr/sites/vprwww/files/uploaded_files/COVID-19/2-10-RoutinePracticesFinal-20190123.pdf)
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The PI and study team member(s) should work with appropriate research site representatives to ensure sufficient supply of PPE, including gloves, masks, and disinfectant wipes. All steps outlined in [KSHC IPAC Resource: Guide for Accessing PPE at KHSC Sites](https://www.queensu.ca/vpr/sites/webpublish.queensu.ca.vprwww/files/files/COVID-19/Guide-for-accessing-PPE-at-KHSC-Sites_April%2020-2020_.pdf)at *KHSC Sites, PCH and 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. SIGNATURES**

*Investigator:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| PI Name |  | PI Signature |  | Date |

*Approved by:*

 Dr. Steven Smith

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Vice-Dean, Health Sciences Research, Queen’s UniversityVice President, Research, Kingston Health Sciences Centre |  | Signature |  | Date |