Hospital Departmental Impact & Information Form (Version January 2021)

Please complete this form for Hospital-based Research. Researchers are to complete this form **IF** they checked "YES" to Question 1.6 in the TRAQ DSS FORM. Check out "***Tips Sheet for Completing TRAQ DSS FORM for Hospital-based Research***" to confirm whether your project is considered "Hospital based-Research".

Information from this form will provide hospital departments the information they need to determine if they can support the study and to ensure smooth and efficient implementation of your research project.

Please **attach** this form along with your research study proposal/protocol/summary and budget/budget justification (if applicable) to the TRAQ DSS FORM under "**Attachments**". Draft versions of the documents are acceptable. All of these documents are required before any Hospital Operational Director(s)/Research Director(s) can approve a TRAQ DSS FORM. Check out "***Tips Sheet for Completing Hospital Departmental Impact & Information Form***" for assistance with completing this form.

PRINCIPAL INVESTIGATOR (please identify):

CATEGORY OF STUDY (please check one): ☐ academic/investigator-initiated ☐ industry-sponsored

PRIMARY CONTACT PERSON FOR QUESTIONS ABOUT STUDY:

NAME: TITLE:

EMAIL: TELEPHONE:

TITLE OF STUDY/STUDY PROTOCOL # (if applicable):

Please ensure that you answer the following questions by including all relevant information for each hospital department identified on the TRAQ DSS FORM under the "Approval" tab:

A. Please include a plain language abstract of your project of a maximum of 300 words as submitted to the HSREB or in a similar format.

B. Is your research occurring in a designated research area in the hospital, including the WJ Henderson Centre for Patient-Oriented Research?

Yes ☐ No ☐ If Yes, please specify the area, and complete the remainder of the form as applicable.

C. Briefly describe how your research project will impact the various hospital departments, if applicable.

If not applicable, please check ALL that apply:

☐ NOT APPLICABLE (only research funds will be held in the hospital/hospital research institute. The research project and/or the location of the research team is not within the hospital)

☐ NOT APPLICABLE (research will only be occurring in your designated research areas within hospital)

D. Will hospital inpatients and/or outpatients be recruited to participate in this study?

Yes ☐ No ☐

E. If you answered "YES" in Question D, which hospital program(s), service(s) and/or clinic(s) will they be recruited from? Please remember to also select the correct Hospital Operational Director(s) (HOD) under the Approvals tab of your TRAQ DSS FORM prior to submission.

F. Is the Program Manager of the hospital program(s), service(s) and/or clinic(s) where your research will be conducted aware of your research proposal? Please note that Program Managers are not listed under the Approvals tab. Please contact Lisa McAvoy at Lisa.McAvoy@kingstonhsc.ca for the name(s) of the relevant Program Manager(s) at KHSC or Sally Lake lakes@providencecare.ca for Program Managers at PC.

Yes ☐ No ☐ If No, please clarify below. Not applicable ☐

G. If you answered "YES" to Question F, is the Program Manager supportive of any additional work required by hospital staff?

Yes ☐ No ☐ If No, please clarify.

H. Will you verify each hospital inpatients' and/or outpatients' medical records to confirm that they have not removed their consent to be contacted for research before you approach a potential participant or use the participant's personal data from KHSC's PCS (i.e. chart review)? Contact PC Medical Records for their policy.

Note: ➢ At KHSC you are required to verify that a patient hasn't removed their consent to be contacted for research. See Accessing Medical Records for Research Roadmap on the KGHRI website: https://kingstonhsc.ca/research/researchers-staff-trainees

Yes ☐ No ☐ Not applicable ☐

I. Will you approach hospital inpatients and/or outpatients about their potential participation in the research project?

Yes ☐ No ☐ Not applicable ☐

If you answered "YES" to Question I, please identify all individuals who will approach potential hospital inpatients and/or outpatients about their participation in the research project.

J. Please specify the exact hospital resources (staff, equipment, supplies, space, medications, procedures/testing, etc.) needed beyond usual care currently being provided to patients, if applicable.

If not applicable, please check ALL that apply:

☐ NOT APPLICABLE (only research funds will be held in the hospital/hospital research institute. The research project and/or the location of the research team is not within the hospital)
☐ NOT APPLICABLE (hospital resources needed are only usual care)
☐ NOT APPLICABLE (research will only be occurring in your designated research areas within hospital)

K. Please specify how the use of these hospital resources (staff, equipment, supplies, space, medications, procedures/testing, etc.) will be reimbursed to the individual hospital(s), if applicable.

If not applicable, please check ALL that apply:

☐ NOT APPLICABLE (only research funds will be held in the hospital/hospital research institute. The research project and/or the location of the research team is not within the hospital)
☐ NOT APPLICABLE (hospital resources needed are only usual care)
☐ NOT APPLICABLE (research will only be occurring in your designated research areas within hospital)

L. Please check off the type(s) of research activities that hospital staff employees will be responsible for carrying out in individual hospital department(s), if applicable:

- ☐ Study recruitment
- ☐ Specimen collection (e.g. Blood/Fluids/Tissue/Swabs)
- ☐ Specimen processing/lab analysis
- ☐ Study documentation
- ☐ Vitals collection (e.g. BP, HR, RR, WT, HT)
- ☐ Medication administration
- ☐ Distribution/collection of self-administered questionnaires
- ☐ Administering questionnaires
- ☐ Informed consent process
- ☐ Pharmacy medication preparation/storage/monitoring
- ☐ ECG/EEG/ECT/TMS/EMG
- ☐ Direct care/exam
- ☐ Data analysis
- ☐ Other (please indicate below)

If not applicable, please check ALL that apply:

- ☐ NOT APPLICABLE (only research funds will be held in the hospital/hospital research institute. The research project and/or the location of the research team is not within the hospital)
- ☐ NOT APPLICABLE (only research staff will carry out activities within individual hospital departments)
- ☐ NOT APPLICABLE (research will only be occurring in your designated research areas within hospital)

M. Please check off the type(s) of research activities that research staff will be responsible for carrying out in individual hospital department(s), if applicable:

- ☐ Study recruitment
- ☐ Specimen collection (e.g. Blood/Fluids/Tissue/Swabs)
- ☐ Specimen processing/lab analysis
- ☐ Study documentation
- ☐ Vitals collection (e.g. BP, HR, RR, WT, HT)
- ☐ Medication administration
- ☐ Distribution/collection of self-administered questionnaires
- ☐ Administering questionnaires
- ☐ Informed consent process
- ☐ Pharmacy medication preparation/storage/monitoring
- ☐ ECG/EEG/ECT/TMS/EMG
- ☐ Direct care/exam
- ☐ Data analysis
- ☐ Other (please indicate below)

If not applicable, please check ALL that apply:

- ☐ NOT APPLICABLE (only research funds will be held in the hospital/hospital research institute. The research project and/or the location of the research team is not within the hospital)
- ☐ NOT APPLICABLE (only hospital staff will carry out activities within individual hospital departments)
- ☐ NOT APPLICABLE (research will only be occurring in your designated research areas within hospital

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N. Please specify whether access to Medical Records are needed.

Yes ☐ No ☐

If Yes to Question N, please check off all applicable:

☐ Access to PCS (KHSC electronic medical records)

☐ Access to other hospital electronic databases Please specify:

☐ Access to paper medical records (chart pull) NOTE: All paper medical records for KHSC are stored off-site and a $15 charge per chart will be billed. Contact PC Medical Records for applicable charges.

☐ Request data pull of patient data (use of Decision Support)

If Yes to Question N, do you need Medical Records stored beyond the KHSC 09-180 Policy (Patient Records: Medical Records Retention/ Destruction), for your research requirements, e.g. 25 years as per Health Canada regulations)? Contact Linda Reason, Policy Coordinator at reasonl@providencecare.ca for PC Policy Inquiries.

Yes ☐ No ☐

* Researchers are required to consult with Medical Records as early as possible with respect to storage/retention needs for research.

O. Will research participants undergo an informed consent process?

Yes ☐ No ☐ Not applicable ☐

P. If you answered "YES" to Question O, please identify all individuals who will carry out the informed consent process.

Q. If you answered "YES" to Question O, please explain how patient confidentiality will be protected, in compliance with applicable privacy legislation, during the consenting process?

R. Please describe how the research activities will be coordinated within the existing workflow in individual hospital department(s), if applicable. Please specify how expectations of staff will be integrated into the workflow. Refer to specific sections of the protocol/proposal and provide plain language explanations. Please note that more complete information can help expedite review.

If not applicable, please check ALL that apply:

- ☐ NOT APPLICABLE (only research funds will be held in the hospital/hospital research institute. The research project and/or the location of the research team is not within the hospital)
- ☐ NOT APPLICABLE (research will only be occurring in your designated research areas within hospital)

S. Do all members of your research team hold a Research Hospital Appointment at the hospital location(s) where the research is occurring if they are not paid research employees of the Hospital or hold hospital privileges (i.e. clinicians)?

Yes☐ No☐ If No, please clarify.

T. Please provide any additional information that may be relevant to assist hospital operational directors in making a decision about approval for your research project.

If not applicable, please check ALL that apply:

- ☐ NOT APPLICABLE (only research funds will be held in the hospital/hospital research institute. The research project and/or the location of the research team is not within the hospital)
- ☐ NOT APPLICABLE (research will only be occurring in your designated research areas within hospital)

U. Will you be using the W J Henderson Centre for Patient Oriented Research (WJHCPOR) on Connell 4?

Please note: to access the Centre for Clinical Research/Clinical Trials all study team members (PIs, study nurses, study coordinators, students and trainees) are required to complete various training. (e.g., WJHCPOR General Orientation Training, Good Clinical Practice (GCP) and Health Canada Division 5 training if conducting Drug Trials, WJHCPOR Lab training and Queen's Biosafety Training if using the Centrifuge Room and/or Freezer Room). Contact Lisa McAvoy Lisa.McAvoy@kingstonhsc.ca for more information regarding training.

Yes ☐ No ☐ Not applicable ☐

Please check off the rooms/equipment you will be using to carry out your research (rooms marked with an (*) must be booked through KHSC email Outlook Calendar):

- ☐ Interview Room *
- ☐ Exam Room *
- ☐ Clinical Investigation Unit Infusion Chair *
- ☐ Minor Procedure Room *
- ☐ Meeting Room
- ☐ Centrifuge Room *
- ☐ Cardiac Monitor
- ☐ Clinical Investigation Unit Bed *
- ☐ Short term freezer Room (Max. 12 Months)
- ☐ SpO Monitor
- ☐ ECG Machine

REMINDER NOTES:

- ✓ Some hospital departments may require additional information to be collected before approval will be granted. If additional information is required, the hospital operational director(s)/research director(s) will reach out to you once your TRAQ DSS FORM is submitted and received in their queue.

- ✓ It is important to consult (*reach out via email or telephone*) with hospital operational director(s)/research director(s) early in your proposal/protocol and budget development to ensure budgets are accurate when applying for grants or negotiating industry contracts and hospital resources are required.

- ✓ If there is urgency for your TRAQ DSS FORM to be reviewed and approved, please reach out to the respective hospital operational director(s)/research director(s) via email or telephone to let them know. TRAQ DSS FORMS are to be submitted at least 15 business days before any internal/external deadlines to ensure all approvals are in place.

- ✓ Researchers are to have all necessary certifications (i.e. human ethics, animal care, biohazards, and radiation) and TRAQ DSS FORM approvals in place before commencing research projects. Once all necessary certifications are in place, please upload all approval letters to your TRAQ DSS FORM to ensure all hospital operational director(s)/research director(s) can obtain a copy.

- ✓ Researchers using hospital labs, pharmacy, and/or clinical engineering are required to complete the additional study request form and attach to their TRAQ DSS FORM prior to submission under "Attachments".

- ✓ For requests to KHSC Decision Support, please complete the KHSC Decision Support Data Request Form.