

Tips for Completing the Hospital

Departmental Impact & Information Form (version January 2021)

- Log into the **TRAQ Researcher Portal** (<http://www.queensu.ca/traq/signon.html>)
- Click on **Useful Links** at the top right-hand corner
- Click on **AWARDS - Hospital Department Impact & Information Form** link to open the form, which can be completed and saved to your shared drive and attached to the TRAQ DSS FORM application
- Complete the form, as described below

Alternatively,

- Log into the **TRAQ Researcher Portal** (<http://www.queensu.ca/traq/signon.html>)
- Click **Apply New**
- Under **Awards**, click **TRAQ DSS FORM**
- Once you open **TRAQ DSS FORM**, under **Attachments** Tab, click **Hospital Departmental Impact and Information Form** link to open the form, which can be completed and saved to your shared drive and attached to the TRAQ DSS FORM application
- Complete the form, as described below

Page 1: Project Identifiers

- Provide the PI Name, Title of Project, Study Protocol Number (if available) and indicate if Project is academic/investigator-initiated or industry-sponsored
- Provide the Contact Info for person who can provide more details if requested

A. Please include a plain language abstract of your project (max. 300 words)

- Can be plain language abstract submitted in your HSREB application.

B. Is your research occurring in a designated research area in the hospital?

- “Yes” or “No” response
- Specify the area where your research will be occurring.

C. Briefly describe how your research will impact various hospital departments

Please provide a basic overview of how the project will impact the various hospital departments. For example:

- How many and which type of patients will you be approaching to recruit as potential participants?
- What clinics, surgery or other hospital space you will be entering to recruit, consent, distribute or administer questionnaires/surveys, collect specimens, carry out testing, etc.?
- How often you will be entering the clinics, surgery or other hospital space for these purposes (e.g. daily, weekly, monthly)? For how long? Include the expected duration (*i.e. 4 weeks*) and end date of study (*i.e. Spring 2021*).
- Will you require hospital staff to assist and/or will your research staff/students/trainees be carrying out the various research activities in the hospital space?
- Will you need to access medical records for subject recruitment purposes or data collection?
- Will you require laboratory services to process, store or ship your biological samples/specimens (if YES, please complete the “KHSC Laboratory Services Study Request Form” and attach it to TRAQ DSS FORM)?



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- Will you require access to the clinics, surgery or other hospital space to collect biological samples/specimens/discarded tissue, which will be transported back to your laboratory within the hospital or on Queen's campus (e.g. Botterall Hall, Cancer Research Institute, School of Kinesiology)?
- Will you require pharmacy services to receive, store, prepare, administer, or monitor a study drug (if YES, please complete the "KHSC Pharmacy Services Study Request Form" and attach to TRAQ DSS FORM)?
- Will your research project use medical equipment (i.e. hospital-owned, researcher-owned, Industry-owned) in KHSC (if YES, you are required to complete the "KHSC Clinical Engineering Services Study Request Form" and attach to TRAQ DSS FORM)?
- Will your project require Decision Support services to find your participants and/or pull patient data?

NOTE: These are some examples. If your project does not impact ANY clinical areas or KHSC/PC services, check the appropriate boxes listed under Section C

D. Use of hospital inpatients and/or outpatients for research proposal

- "Yes" or "No" response

E. Where are the inpatients/outpatients recruited from?

- If you answered "Yes" to Question D, provide information about which hospital program(s), service(s) and/or clinic(s) inpatients and/or outpatients will be recruited from
- If you answered "No" to Question D, leave the box blank or indicate "not applicable"

F. Program Manager aware of your research proposal?

- "Yes" or "No" or "Not applicable" response
- If "No", explanation required
- If you answered "Yes" to Question D, indicate if Program Manager is supportive of any additional work required by hospital staff?
- Program Managers are not listed under the Approvals tab. Please consult the current KHSC Organizational Chart or contact Lisa McAvoy at Lisa.McAvoy@kingstonhsc.ca for the name(s) of the relevant Program Manager(s).
- Contact Providence Care Research Institute: Sally Lake, 613-544-4900 ext. 53494, lakes@providencecare.ca for PC Program Manager contact information.

G. Program Manager supportive of additional work?

- "Yes" or "No" response

H. Verification of medical records to ensure patient consented to be contacted for research

- "Yes" or "No" or "Not applicable" response
- 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>



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I. Approaching hospital inpatients/outpatients about participation in research project

- “Yes” or “No” or “Not applicable” response
- If you answered “Yes” to Question I, identify all individuals who will approach inpatients/outpatients about their potential participation in a research project

J. Specify exact hospital resources needed beyond usual care/standard of care

Please provide details on the specific hospital resources required (staff, equipment, supplies, space, medications, testing, etc.) that are beyond usual care/standard of care. For example, do you require:

- Additional phlebotomy services for blood draws that are above standard of care (e.g. need pre- and post-PK blood draws, DNA, RNA blood draws every study visit, or more often than standard of care visits)?
- An ECG technician to perform ECGs that are above standard of care (e.g., 3 ECGs 2 minutes apart per study visit)?
- The laboratories to process and analyze biological samples/specimens above standard of care (e.g. additional test or bloodwork every study visit when standard of care is certain tests only every 6 months)?
- The use of hospital equipment (e.g. weigh scales, vitals machines, IV pump), supplies and/or medications for research purposes?
- Annual certification and maintenance checks of standard of care medical equipment used in clinical trials?
- Pharmacy services to receive, store, enter in IVRS system, prepare, etc. study drugs as part of your study?
- A certain piece of surgical equipment, device or product to be used more often for your research project on patients when the standard of care is another brand?
- Hospital staff to carry out any of your various research activities during their normal work hours for the delivery of patient care?

NOTE: These are some examples. If your project does not require any KHSC/PC resources beyond usual/standard of care, check the appropriate boxes listed under Section J

K. Specify how the use of hospital resources will be reimbursed

- For Hospital-based research projects, you must provide a description of how you plan to reimburse the hospital for the additional costs above and beyond the usual care/standard of care. Research study budgets should include these costs.

It is important for researchers to consult early with the various hospital departments (Hospital Operational Directors (HODs)) to get an estimate (e.g. lab, pharmacy, clinical engineering, and imaging costs, salary and benefit recovery for hospital staff used, supplies, equipment, and medication costs) to help develop their budgets. The TRAQ DSS FORM MUST be submitted at least 15 business days in advance of the funding agency deadline. It is also recommended that PIs consult with HODs well in advance of the deadline (> 1 month) to discuss any issues involving impact on patient flow, budgeting for hospital services and cost recovery, etc.

- To contact one of the HODs or Research Directors, please check out these links for a complete list of emails and telephone numbers: <http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents> and <http://www.kgh.on.ca/research/researchers-staff-trainees>.



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- Hospital department(s) will invoice the researcher and costs can be recovered from researchers' research accounts set up for the project at Queen's or one of the hospitals/hospital research institutes.

NOTE: If none of the above is applicable, check the appropriate boxes listed under Section K.

L & M. Check off type of research activities to be carried out by hospital staff and/or research personnel

- Check off all boxes applicable related to research activities that will be carried out by hospital staff and/or research staff, students and/or trainees (research personnel) within hospital departments for your study.

NOTE: If none of the above is applicable, check the appropriate boxes listed under Section L and Section M.

N. Medical Records / Medical Records Retention

- "Yes" or "No" or "Not applicable" response
- If you answered "Yes" to Question N, check all applicable types of access you require.
- Charges for paper chart pulls vary by Institution (contact Medical Records at KHSC and/or PC for current cost)
- If you answered "Yes" to Question N, do you need Medical Records stored beyond the KHSC (Patient Records: Medical Records Retention/S\ Destruction) Policy, for 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" or "No"
- If you answered "Yes" to needing medical records to be archived for research purposes, please consult with Medical Records as early as possible.

O. Informed Consent

- "Yes" or "No" or "Not applicable" response

P. Identify Individuals carrying out Informed Consent

- If you answered "Yes" to Question O, identify all individuals who will carry out the informed consent process

Q. Patient Confidentiality

- If you answered "Yes" to Question O, explain how patient confidentiality will be protected during consent process



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R. Describe how the research activities will be coordinated within the existing flow

Describe how your research activities will be coordinated within the various hospital departments and impact existing patient care flow. For example:

- The research coordinator will approach patients during their outpatient clinic visit at the hospital and ask if they are interested in hearing more about the study while they are waiting to see the physician. Consenting and study testing procedures will take place in the outpatient clinic visit area by the research coordinator but will not impact the standard of care visit.
- The research coordinator will review patient charts of study participants. At a designated hospital workstation or at their research office, they will extract data from the participant's medical charts related to bloodwork and imaging tests already completed as part of their standard of care.
- During a normal standard of care visit, the phlebotomist will take an extra two vials of blood during their normal collection for the research study. Vials will be provided by the research coordinator.
- A research coordinator will come to the laboratories and/or surgical areas and collect biological specimens to be processed and analyzed at a research laboratory located in Botterell Hall.

NOTE: If your research activities will not be conducted in clinical areas or hospital departments, check the appropriate box listed under Section R.

S. Research Hospital Appointments

- "Yes" or "No" response
- If "No", explanation required

T. Provide any additional information

- Please provide any additional information that may be relevant to assist the various hospital operational directors in making a decision to approve your study

NOTE: If none of the above is applicable, check the appropriate box listed under Section T.

U. W. J. Henderson Centre for Patient Oriented Research

- "Yes" or "No" response "Not applicable" response
- Check off all boxes applicable related to rooms/equipment that will be used to carry out your research by hospital staff and/or research staff, students and/or trainees (research personnel) within the W J Henderson Centre for Patient Oriented Research.



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Need Help?

- For questions regarding Hospital-based Research, please contact:
 - Kingston General Health Research Institute-KGH and HDH Site: Lisa McAvoy, 613-549-6666 ext. 3344, Lisa.McAvoy@kingstonhsc.ca
 - Providence Care Research Institute: Sally Lake, 613-544-4900 ext. 53494, lakes@providencecare.ca
- To access the “**KHSC Laboratory Services Study Request Form**”, “**KHSC Pharmacy Services Study Request Form**” or “**KHSC Clinical Engineering Services Study Request Form**”, please check out these links: <http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents> or <http://www.kgh.on.ca/research/researchers-staff-trainees>.
- To contact one of the HODs or Research Directors, see the contact information listed at: <http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents> or <http://www.kgh.on.ca/research/researchers-staff-trainees>.
- For general inquiries or technical issues with the TRAQ system, please contact the TRAQ Help Desk. The TRAQ Help Desk is available by email traq@queensu.ca or phone: Queen’s ext. 78426.



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