Tips for Completing the Hospital Departmental Impact & Information Form

- Log into the TRAQ Researcher Portal (<u>http://www.queensu.ca/traq/signon.html</u>)
- o 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,

- o Log into the TRAQ Researcher Portal (http://www.queensu.ca/traq/signon.html)
- o 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 of a maximum of 300 words as submitted to the HSREB or in a similar format.

This will be useful to the reviewer before proceeding to the remaining questions in the form

B. 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 will you 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 2017*).
- 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)?
- Will you require access to the clinics, surgery or other hospital space to collect biological samples/specimens, which will be transported back to your laboratory within the hospital or on Queen's campus (e.g. Botterell 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, please 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: If none of the above is applicable, check the appropriate boxes listed under Section A.

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

"Yes" or "No" response

D. Where are the inpatients/outpatients recruited from?

- If you answered "Yes" to Question B, 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 B, leave the box blank or indicate "not applicable"

E. Program Manager aware of your research proposal?

- "Yes" or "No" or "Not applicable" response
- If "No", please explain

F. Program Manager supportive of your research proposal?

- If you answered "Yes" to Question D, indicate if Program Manager is supportive of any additional work required by hospital staff?
- If "No", please explain

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

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

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

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

I. Who will be approaching hospital inpatients/outpatients?

"If you answered "Yes" to Question G, 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

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

- Additional phlebotomy services for blood draws that are beyond usual care (e.g. need pre- and post-PK blood draws, DNA, RNA blood draws every study visit, or more often than usual care)?
- > An ECG technician to perform ECGs that are beyond usual care (e.g., 3 ECGs 2 minutes apart per study visit)?
- The laboratories to process and analyze biological samples/specimens beyond usual care (e.g. additional test or bloodwork every study visit when usual care is limited to specific tests only every 6 months)?
- > The use of hospital equipment (e.g. IV pump), supplies and/or medications beyond usual care?
- > Certification and maintenance checks of medical equipment used in research?
- > 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 usual 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: If none of the above is applicable, check the appropriate boxes listed under Section I.

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

- For Hospital-based research projects, please provide a description of how you plan to reimburse the hospital for the additional costs above and beyond usual 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 should be submitted at least 15 business days in advance of the funding agency deadline to avoid delays in obtaining the necessary Approvals. 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: <u>http://www.queensu.ca/traq/awards-grants-contracts/supportive-</u> <u>documents</u> and <u>http://www.kqh.on.ca/research/researchers-staff-trainees</u>.
- 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 J.

K. and L. 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 K and Section L.

M. Informed Consent Process

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

N. Individuals conducting informed consent process

If you answered "Yes" to Question M, identify all individuals who will carry out the informed consent process with inpatients/outpatients

O. Patient confidentiality

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

P. 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 usual 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 usual care.
- During a typical visit for usual care, 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 none of the above is applicable, check the appropriate boxes listed under Section P.

Q. Research Hospital Appointments

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

R. 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 boxes listed under Section R.

R. Provide any additional information

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

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

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.

Need Help?

- For questions regarding Hospital-based Research, please contact:
 - Kingston General Health Research Institute: Lisa McAvoy, 613-549-6666 ext. 3344, <u>Lisa.McAvoy@kingstonhsc.ca</u>
 - Hotel Dieu Hospital Kingston Research Institute: Shari Glustein, 613-544-3400, ext. 2115, <u>Shari.Glustein@kingstonhsc.ca</u>
 - Providence Care Research Institute: Sally Lake, 613-544-4900 ext. 53494, <u>lakes@providencecare.ca</u>
- 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: <u>http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents</u> or <u>http://www.kqh.on.ca/research/researchers-staff-trainees</u>.
- To contact one of the HODs or Research Directors, see the contact information listed at: <u>http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents</u> or <u>http://www.kgh.on.ca/research/researchers-staff-trainees</u>.
- For general inquiries or technical issues with the TRAQ system, please contact the TRAQ Help Desk. The TRAQ Help Desk is available by email <u>traq@queensu.ca</u> or phone: Queen's ext. 78426.







