HOSPITAL-BASED RESEARCH
FREQUENTLY ASKED QUESTIONS (FAQ)

TRAQ DSS FORM: FAQ for Hospital-based Research

What is considered Hospital-based Research?

If your research meets ANY of the following criteria, check "YES" to Question 1.6 within the **TRAQ DSS FORM**:
- ➢ Research occurs in a hospital setting;
- ➢ Research utilizes or requires hospital staff, space, services and/or other resources;
- ➢ Research offices for yourself and/or your research staff/students/trainees are located in a hospital setting OR your research lab, unit, centre, space, and/or equipment is located in a hospital setting, even if your research project is occurring off-site;
- ➢ Research involves obtaining or retrieving patient biological samples/specimens from patients seen (or samples stored) at one of the hospitals for lab projects and transported to your research lab located within OR outside of the hospital (i.e. Botterell Hall, CRI);
- ➢ Research involves extracting patient data from hospital medical records;
- ➢ Research involves purchasing supplies or equipment at/through the hospitals;
- ➢ Research involves the use of hospital services and payment to hospital departments;
- ➢ Research funds will be held within one of the hospitals/hospital research institutes.

INFORMATION SHEET: *For more information about completing a TRAQ DSS FORM for Hospital-based Research, please check out these links for a new "Tips Sheet for Completing TRAQ DSS FORM for Hospital-based Research":* http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents *and* http://www.kgh.on.ca/research/researchers-staff-trainees.

Who are the appropriate Hospital Operational Directors and Research Directors?

If your answer is "YES" to Question 1.6 in the **TRAQ DSS FORM**, you MUST select the appropriate Research Director(s) to approve based on which hospital(s) are impacted and selected under Questions 3.1-3.3. Research Directors are as follows for the hospital sites: KHSC-HDH - Vic Sahai, KHSC-KGH - Veronica Harris-McAllister, PC - Kathleen Fitzpatrick. You MUST also identify ALL hospital departments that will be impacted by your research on the "Other Approvals" under the APPROVALS tab. You must check off the hospital department even if you or your research staff/students/trainees are the ones accessing the space (versus Hospital staff) and carrying out the research activities OR if the study involves usual care/standard of care. The hospital departments need to be made aware of any impact to the flow of patient operations even if hospital staff and resources are not used.

When should I submit a TRAQ DSS FORM?

Only the Principal Investigator (a Faculty Member) can submit a **TRAQ DSS FORM**. A TRAQ DSS FORM* MUST be completed: (1) if you are applying for any internal or external research funding, (2) if there are no funds and no contracts associated with your research project (certifications only required) AND your research is considered Hospital-based Research as HODs & Research Directors' signoff is required, OR (3) if you require legal review of your agreements/contracts. 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 to ensure all hospital approvals are in place. 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, preparing a human ethics review submission, etc.

***Internal FHS/KGH Research Institute granting competitions**: If your project involves funds that will be held at BOTH Queen's <u>AND</u> the KGH Research Institute (KGHRI), then you are required to complete a TRAQ DSS FORM for each internal funding grant (i.e. complete two TRAQ DSS FORMs; one for Queen's & one for KGHRI) for the same project. If only one institution is administering (holding) the funds, only 1 TRAQ DSS is required per project. If unsure, please reach out to one of the TRAQ or KGHRI contacts listed under "Need Help?" at the end of this document.*

What documents need to be attached to TRAQ DSS FORM prior to submission?

For Hospital-based Research projects, researchers <u>MUST</u> attach the following documents with their **TRAQ DSS FORM** prior to submission:
- Research proposal or study protocol (draft version accepted);
- Budget or budget justification (if applicable, draft version accepted);
- Hospital Departmental Impact & Information Form;
- KHSC Laboratory Services Study Request Form if using KHSC lab services for ANY biological samples/specimens used in your research project (standard of care **AND/OR** above standard of care);
- KHSC Pharmacy Services Study Request Form if using KHSC pharmacy services for ANY drug monitoring, storage, mixing or blinding in your research project (standard of care **AND/OR** above standard of care);
- KHSC Clinical Engineering Services Study Request Form if using ANY medical equipment (hospital-owned, researcher owned, and/or industry-owned (vendor)) in KHSC for your research project.

Other important documents to upload, if applicable:
- For research projects involving an Informed Consent Form, please upload if available;
- For research projects working with industry (vendor) or other academic partners outside of Queen's and/or local hospital(s)/hospital research institute(s) that require legal review of an agreement/contract, please upload the Study Agreement so that the contract review process can commence at Queen's;
  - <u>Future Study Agreement Amendments</u>: *Please log into TRAQ and under your Applications (post review), add an event to your TRAQ DSS FORM file. Click on EVENTS tab and select the AMENDMENT FORM link. Complete the Amendment Form and upload an electronic version of the Amendment contract and submit. This will initiate the review of the amendment by Queen's.*
- Investigator Brochure or Product Monograph, if available (industry-sponsored clinical drug trials);
- HSREB, CTO and/or OCREB certification approval letter, if already obtained;
- Overhead Waiver Form, if applicable (http://www.queensu.ca/secretariat/policies/research/indirect.html).

   PLEASE ENSURE ALL DOCUMENTS ARE UPLOADED TO THE TRAQ DSS FORM PRIOR TO SUBMISSION.

I have submitted a HSREB application with all my documents, why do I need to attach them to my TRAQ DSS FORM?

HODs & Research Directors DO NOT have access to the HSREB information and therefore do not have a complete picture of the proposed study and the proposed flow of patients/participants within and outside the hospitals for their visits. You <u>MUST</u> include the documents listed above and attach the files to your **TRAQ DSS FORM** under the "Attachments" Tab. These documents are required before ANY HOD and/or Research Director can sign-off. The combination of supporting documents and the revised Hospital Department Impact and Information Form attached to a TRAQ DSS FORM will help to expedite the hospital review process. Once signed off, the file will be forwarded to your Queen's Department Head for approval.

The approvals process is as follows:

| PI submits TRAQ DSS | → | Hospital Signing Authority | → | Departmental Signing Authority | → | Faculty Signing Authority | → | URS Receives TRAQ DSS |
| | | HODs & Research Directors | | Queen's Department Head | | Queen's Faculty Representative | | University Research Services @ Queen's |

* If the documents are not attached to your TRAQ DSS FORM, you will need to email the documents to the HODs & Research Directors separately before your application will be reviewed and approved. To contact one of the HODs or Research Directors, please see the contact information available at: http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents *or* http://www.kgh.on.ca/research/researchers-staff-trainees*.*

What do I put in the budget/sponsor information section?

If there are funds to be received for your project, you need to indicate the amount of funding you will be requesting from the agency by completing a "funding disbursement" screen. Start by clicking on "**Add New**" at the bottom of the Sponsor Info screen. Enter the anticipated start date of your project, the fiscal year data field above will automatically populate. Enter the total amount of requested cash (this amount should include the overhead if applicable), or expected in-kind contribution. You can indicate 'draft' in the notes section on this page; if your project receives funding, the final budget will be verified prior to submission to Research Accounting. If your study is a clinical trial, please provide an estimate budget by multiplying the estimated number of subjects by the case cost per subject.   If you are applying for an overhead waiver please also note this in the comments section and upload your signed waiver form to your TRAQ DSS FORM.

Why do I have to link my pending human ethics certifications to my application? If I don't get the funding I'm not doing the project!

Pending certification(s) still need to be linked even if you are not applying to an ethics review system (HSREB, CTO, OCREB) at the time of your submission to a granting agency. You will need to have your certifications in place before you can commence your research or open a research account. Thus, linking your pending certifications in your TRAQ DSS FORM can help to avoid delays in starting your research or opening a research account once your grant or contract is funded. Please remember to check off in the TRAQ DSS FORM the type of ethics review (i.e. HSREB, OCREB or CTO) being used for your project. The TRAQ DSS FORM also captures all of your HODs & Research Directors and Department Head approvals, which are required when submitting to a granting agency or having an agreement reviewed by the Queen's Industry Partnership Office. Please remember to Click "**Add New"** under **Related Certifications** to make note of HSREB/CTO/OCREB certifications submitted OR your intention to submit to these review committees.

There is no funding for my project and I am applying to HSREB for human ethics review only: do I need to complete a TRAQ DSS FORM?

Yes. All researchers conducting Hospital-based Research <u>MUST</u> complete a **TRAQ DSS FORM**, even if there are no funds administered (i.e. "*No Funds, No Contract Reviewed*" as Program drop down option) for your research project. The TRAQ DSS FORM captures all of your HODs, Research Director(s), Department Head, and Faculty approvals.

Hospital Departmental Impact and Information Form (HDIIF)

The Hospital Departmental Impact and Information Form (HDIIF) provide information for the hospitals to review that helps expedite approvals of a TRAQ DSS FORM for Hospital-based Research. ALL researchers conducting Hospital-based Research MUST complete and upload the HDIIF to their "**TRAQ DSS FORM**" as an attachment prior to submission. Information from this form provide Hospital Operational Directors (HODs) & Research Directors the additional information they need (i.e. how your research project will impact the flow of patient care in hospitals) that cannot be easily found in budgets and study proposals/ protocols to facilitate the hospital approval process.

INFORMATION SHEET: *To access the HDIIF or for more information about how to complete a HDIIF for Hospital-based Research, please see the new "**Tips Sheet for Completing the HDIIF**". Both documents are available at: http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents or http://www.kgh.on.ca/research/researchers-staff-trainees.*

KHSC Laboratory Services Study Request Form

ALL researchers conducting Hospital-based Research and require the services of the KHSC Core Labs for ANY biological samples/specimens used in your research project (standard of care **AND/OR** above standard of care) MUST complete and upload the "KHSC Laboratory Services Study Request Form" to their "**TRAQ DSS FORM**" as an attachment prior to submission.

INFORMATION SHEET: *To access the KGH/HDH Laboratory Services Study Request Form, please check out these links: http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents and http://www.kgh.on.ca/research/researchers-staff-trainees.*

KHSC Pharmacy Services Study Request Form

ALL researchers conducting Hospital-based Research and require the services of the KHSC Pharmacy for ANY drug monitoring, storage, mixing or blinding in your research (standard of care **AND/OR** above standard of care) MUST complete and upload the "KHSC Pharmacy Services Study Request Form" to their "**TRAQ DSS FORM**" as an attachment prior to submission.

INFORMATION SHEET: *To access the KHSC Pharmacy Services Study Request Form, please check out these links: http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents and http://www.kgh.on.ca/research/researchers-staff-trainees.*

KHSC Clinical Engineering Services Study Request Form

ALL researchers conducting Hospital-based Research and using medical equipment in KHSC (hospital-owned, researcher-owned, industry-owned (vendor) MUST complete and upload the "KHSC Clinical Engineering Services Study Request Form" to their "**TRAQ DSS FORM**" as an attachment prior to submission.

INFORMATION SHEET: *To access the KHSC Clinical Engineering Services Study Request Form, please check out these links: http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents and http://www.kgh.on.ca/research/researchers-staff-trainees*

- For questions regarding Hospital-based Research, please contact:
  - Kingston General Health Research Institute:
    Lisa McAvoy, 613-549-6666 ext. 3344, mcavoye1@kgh.kari.net
  - Hotel Dieu Hospital Kingston Research Institute:
    Shari Glustein, 613-544-3400, ext. 2115, glustes@hdh.kari.net
  - Providence Care Research Institute:
    Sally Lake, 613-548-5567 ext. 5645, lakes@providencecare.ca
- To contact one of the HODs or Research Directors, please 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 questions with the TRAQ system, please contact the TRAQ Help Desk for support. The TRAQ Help Desk is available by email (traq@queensu.ca), or phone: Queen's ext. 78426.