

# Tips for Completing the TRAQ DSS FORM for Hospital-based Research (July 2020)

- Log into the **TRAQ Researcher Portal** (<http://www.queensu.ca/traq/signon.html>)
- Click **Apply New**
- Under **Awards**, click **TRAQ DSS FORM**
- Complete the different tabs of the **TRAQ DSS FORM**, as described below

## Project Info tab

- Give your project a title
- Do not enter the start & end date IF your research funds will be held in Queen's. If your research funds will be held in the hospital/hospital research institute OR if there is no funding associated with the project, then enter start and end dates
- If your project has an international dimension (**your project is occurring in the United States or another foreign country**), note the name of the country(ies) in the **Keywords** textbox
- Click **Search** under **Related Certifications** to link your certifications (human ethics/biohazards/animal care) to your project – if certification is already active, or in progress/under review
- Click **Add New** under **Related Certifications** to make note of any required human ethics/biohazards/animal care certification not yet submitted to a review committee

## Project Team Info tab

- For researchers with cross-appointments: using the **Affiliation** drop down menu select the department/research centre where the project will be taking place
- To transfer role of PI, click **Change PI**, search for PI, click **Select** once PI is identified
- To add team members, scroll down, click **Add New** under **Other Project Team Members\***, click **Search Profiles**, search for team members, click **Select** once team member\*\* is identified

*\* Project Team Members that are external to Queen's may be added in the Comments box (under PI information). However, any team members who should have access to the TRAQ DSS FORM through the Researcher Portal should be added to the Investigator Database and be added to the file under "Other Project Team Members". For an external user to be added to the Investigator Database, please have them go to this "**Self-Registration**" link: <https://eservices.queensu.ca/ROMEO.Researcher.Admin/Researcher/HomePage/UserInfo.aspx>.*

*\*\* Team members who create a TRAQ DSS FORM on behalf of the PI are required to list themselves as a team member before the TRAQ DSS FORM is submitted for approvals.*



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## Project Sponsor Info tab

- Click **Add New** to add sponsor
- Click **Agency** and search for agency's name. When found, click **Select**
- Choose program name from **Program** drop down menu
- For Hospital-based Research where there is no funding and no contracts involved, click **Agency** and search for *[enter hospital/hospital research institute name here]*, click **Select**. Select "No Funds, No Contract Reviewed" from **Program** drop down menu
- Use calendar icon to enter **Competition Date**: *[enter competition date, if applicable, here]*
- Click **Add New** to add funding disbursement: enter anticipated **Start Date** (*estimate*) and total amount requested

## TRAQ DSS FORM tab

### ○ General

- Question 1.1: Identify the location where your research funds will be held
  - If one or more of the three hospitals/hospital research institutes is chosen, please remember to also select the appropriate RESEARCH DIRECTOR(s) on the "Approvals" tab (*i.e. KHSC (KGH or HDH) – Steven Smith; PC – Allison Philpot*), and the hospital operations directors of any hospital departments affected by your research
- Question 1.2: YES/NO answer. Check YES only if you require space in addition to your existing research space assigned
- Question 1.3, 1.4, and 1.5: select the option that applies
- Question 1.6: YES/NO answer. 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, equipment, 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 (*e.g., UHKF funds are required to be administered by the hospital Research Institutes*).



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## o Overhead

- Question 2.1 and 2.2: select the option that applies. If you select OTHER, please provide a justification in the text box provided (e.g. 'Other' → the funding agency does not fund overhead expenses [link to program guidelines]).

## o Hospital Research

- Question 3.1, 3.2, and 3.3: select the options that apply.
- Please identify all hospital departments impacted by your research on the "Approvals" tab, including the appropriate RESEARCH DIRECTOR(s). At a minimum if you said YES to Question 1.6, please select the appropriate RESEARCH DIRECTOR(s) to approve your Hospital-based Research (i.e. KHSC (KGH or HDH) – Steven Smith; PC - Allison Philpot)
- Question 3.4 and 3.5: select the option that applies
- Questions 3.6, 3.7, and 3.8: select the option that applies. This question should be answered for all clinical trials. For Question 3.8, "industry-led" is usually pharmaceutical studies whereas "investigator-led" is usually academic studies.
- Questions 3.9, 3.10, and 3.11: complete the free-form boxes

## o Checklist

- Questions 4.1 and 4.2: select the option that applies. At a minimum, a draft or final research proposal/study protocol AND budget/budget justification (if applicable) should be attached to the TRAQ DSS FORM so that the appropriate HOSPITAL OPERATIONAL DIRECTOR(s)/RESEARCH DIRECTOR(s)/Department Head can review for approval.
- Question 4.3, 4.4, 4.5, 4.6, and 4.7: select the option that applies.
- Question 4.8: select the option that applies. Please attach a Hospital Departmental Impact & Information Form for all Hospital-based Research.

## Attachments tab

- o For Hospital-based Research projects, please attach the following documents with your TRAQ DSS FORM application prior to submission:
  - Research proposal or study protocol (draft version accepted)
  - Budget and 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 for 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 for your research (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 (KGH Site and/or HDH Site) for your research project



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- 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 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 by Queen's
    - Future Study Agreement Amendments: 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, (Request for Variance to Indirect Cost of Sponsored research Policy Form), if applicable (<http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents> ).
- Click **Add Attachment** to attach your document(s).

\* If HSREB, CTO and/or OCREB certification application has not yet been approved, you will be required to provide a copy of the approval letter at a later date by submitting an Amendment Form.

\*\* These forms are available for download at the following links: <http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents> or <http://www.kgh.on.ca/research/researchers-staff-trainees>. Once completed, please attach to your TRAQ DSS FORM prior to submission.

## Approvals tab

- If your answer to Question 1.6 is YES, please select the appropriate RESEARCH DIRECTOR(s) and HOSPITAL OPERATIONAL DIRECTOR(s) to approve your Hospital-based Research ( i.e. KHSC-KGH or HDH – Steven Smith; PC = Allison Philpot). Please identify ALL hospital departments that could be impacted by your research. This includes for example:
  - any inpatient/outpatient clinic(s) and/or surgery space that will be accessed to recruit, obtain consent, gather information or biological samples/specimens from a patient for research purposes, or
  - medical records if accessing/extracting patient data from medical charts or PCS for research project.
- For all hospital departments, you are required to check off the hospital department even if a researcher/research staff/student/trainee is the individual accessing the hospital space and carrying out the research activities (i.e. Hospital staff are not carrying out the research) AND/OR if the study involves usual care. The hospital departments need to be made aware of any impact to their flow of patient operations, even if hospital staff and resources are not being used to assist the research project.
- The Hospitals cannot absorb any costs (i.e. staffing, facilities, diagnostic and lab tests, etc.) associated with Hospital-based Research that are above usual care. Research budgets must include a recovery of costs where hospital departments are impacted.



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## Final Submission

- Click **Submit** button at the top of the screen when ready (Important: PI is the only team member who has access to the Submit button).
- Enter comment (e.g. “Please review.” “For your consideration”) in **Comments** text box, click **Submit** button either at top or bottom of the pop up window

## TRAQ Tips!

- TRAQ** is compatible with the following browsers: Mozilla Firefox, Internet Explorer 7.0+, Safari, and Google Chrome. Internet Explorer 10, 11 users should remember to turn on Compatibility View.
- TRAQ** does not have an automatic save feature. Please click the **Save** button before moving on to the next tab.

## Need Help?

- For more details regarding the TRAQ DSS FORM, please consult the [TRAQ Awards – Researcher User Manual](http://www.queensu.ca/traq/awards-grants-contracts/manuals) available on the TRAQ website (<http://www.queensu.ca/traq/awards-grants-contracts/manuals>).
- For information regarding the Hospital Departmental Impact and Information Form, please consult the *“Tips for Completing the Hospital Departmental Impact & Information Form”*. For more general information about Hospital-based Research, please consult *“Hospital-based Research Frequently Asked Questions (FAQ)”*. Both documents are available at these links: <http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents> or <http://www.kgh.on.ca/research/researchers-staff-trainees>.
- For questions regarding Hospital-based Research, please contact:
  - Kingston General Health Research Institute-KGH/HDH Site: Lisa McAvoy, 613-549-6666 ext. 3344, [Lisa.McAvoy@kingstonhsc.ca](mailto:Lisa.McAvoy@kingstonhsc.ca)
  - Providence Care Research Institute: Sally Lake, 613-544-4900 ext. 53494, [lakes@providencecare.ca](mailto:lakes@providencecare.ca)
- 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](mailto:traq@queensu.ca) or phone: Queen’s ext. 78426.



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