Hospital-based Research and TRAQ DSS FORM

June 6th and 7th, 2016

Topics Covered in Today's Session

- What is considered Hospital-based Research?
- Documents required to be attached to a TRAQ DSS FORM for Hospital-based Research
- Hospital Departmental Impact & Information Form
- Common misses in TRAQ DSS FORMs for Hospital-based Research
- Resources Available
- Research Contacts
- N2 Update: CITI Canada Courses
- Q&A

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What is considered Hospital-based Research?

If your research project meets any of the following criteria:

- **Occurs in a hospital setting or utilizes or requires hospital staff, space, services and/or other resources;**
- **Involves obtaining or retrieving biological samples/specimens from patients seen (or in storage) at one of the hospitals for lab projects and will be transported to your research lab located within OR outside of the hospital (i.e. Botterell Hall, CRI);**
- **Involves extracting patient data from medical charts;**
- **Involves purchasing supplies or equipment at/through the hospitals;**
- **Your research office, research staff/students/trainees, lab, unit, centre, space, and/or equipment is located in a hospital setting even if your research is occurring off site;**
- **Your research funds will be held within one of the hospitals/hospital research institutes.**

If you answered "YES" to any of the above criteria, then you MUST check off "YES" to Question 1.6 within the TRAQ DSS FORM, identify the appropriate hospital operational director(s)/research director(s) for approval, and complete and upload the Hospital Departmental Impact & Information Form to your TRAQ DSS FORM.

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Documents Required to be Attached to a TRAQ DSS FORM for Hospital-based Research

REQUIRED:

- Research proposal/study protocol (*draft accepted*)
- Budget or budget justification (*if applicable, draft accepted*)
- Hospital Departmental Impact & Information Form
- KGH/HDH Laboratory Services Study Request Form if using KGH/HDH lab services for ANY biological samples/specimens for your research (standard of care AND/OR above standard of care samples)
- KGH/HDH Pharmacy Services Study Request Form if using KGH/HDH pharmacy services for ANY drug monitoring, storage, mixing or blinding for your research (standard of care AND/OR above standard of care)

OTHER IMPORTANT DOCUMENTS (*if applicable*):

- For research projects involving an Informed Consent Form (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
- Investigator's Brochure or Product Monograph, if available for industry sponsored clinical drug trials
- HSREB, CTO and/or OCREB certification approval letter, if already obtained
- Overhead Waiver Form, if applicable

**** 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. The TRAQ DSS FORM cannot be pushed back to add these documents until after all HODs have signed off.***

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The TRAQ DSS FORM <u>MUST</u> be submitted at least <u>15 business days</u> in advance of the funding agency deadline to ensure all of your hospital approvals are in place.

It is highly recommended that PIs consult with Hospital Operational Directors well in advance of funding deadlines (> 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.

Hospital Departmental Impact & Information Form

Purpose of the Form: Collection of information for the hospitals that is not easily extracted from your study protocols/proposals. Form covers:

- How your research will impact various hospital departments?
- What specific hospital resources are needed beyond usual care/standard of care?
- How will the use of hospital resources be reimbursed (if applicable)?
- What research activities will be carried out by hospital staff and/or research staff?
- How will the research activities be coordinated within the existing flow of patient care at the hospital?

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Hospital Departmental Impact & Information Form

Section A: How your research will impact various hospital departments?

- *How many and the type of patients you will be approaching to recruit as potential participants for your project?*
- *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)? How long: include expected duration (i.e. 4 weeks) and end date of study (i.e. Spring 2017)?*

If none of the above is applicable, check the appropriate boxes listed under Section A.

Section B: What specific hospital resources needed beyond usual care/standard of care?

- *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).*

If none of the above is applicable, check the appropriate boxes listed under Section B.

Hospital Departmental Impact & Information Form

Section C: How will the use of hospital resources be reimbursed (if applicable)?

- Describe 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.

If none of the above is applicable, check the appropriate boxes listed under Section C.

Section D & E: What research activities will 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 versus research staff/students/trainees (research personnel) within hospital departments for your study.

If none of the above is applicable, check the appropriate boxes listed under Section D & E.

Hospital Departmental Impact & Information Form

Section F: How will the research activities be coordinated within the existing flow of patient care at the hospital? 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.

If none of the above is applicable, check the appropriate boxes listed under Section F.

Section G: Provide any additional information that may be relevant.

Hospital Departmental Impact & Information Form

What should a completed form look like?

- Tips for Completing the Hospital Departmental & Impact Form

Who do I contact to discuss the impact/cost of my research project on various hospital departments?

- Contact List for Hospital Operational Director(s)/Research Director(s)

http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents and http://www.kgh.on.ca/research/researchers-staff-trainees

To help expedite approvals it is recommended that PIs consult with Hospital Operational Directors well in advance of any deadlines (> 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.

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Common Misses in TRAQ DSS FORMs for Hospital-based Research

- **HSREB, CTO and/or OCREB human ethics certification not linked to application**
- **Research staff not listed on Project team tab**
- **Missing information on Project Sponsor tab**
- **Missing or incorrect information on TRAQ DSS FORM tab, for example under "*3. Hospital Research*"**
- **Relevant supporting documents not attached**
- **Appropriate HODs or Research Directors not selected on Approvals tab**

Resources Available

- Tips for Completing TRAQ DSS FORM for Hospital-based Research
- Tips for Completing Hospital Departmental Impact & Information Form
- Hospital-based Research: Frequently Asked Questions (FAQ)
- URS Manuals (http://www.queensu.ca/traq/awards-grants-contracts/manuals)
  - Researcher User Manual
  - Completing and Submitting Event Forms User Manual
  - Submitting a Research Accounting Form User Manual
- URS Videos (http://www.queensu.ca/traq/awards-grants-contracts/videos)
  - Research Accounting Form-Where it is? How do I Complete & Submit it?
  - How to Save and Close an Application (Human Ethics, Biohazard, Awards)
  - Submitting and Tracking Event Forms
  - Transferring PI Roles
  - How to Complete a Budget Template
- Research Roadmap for Hospital-based Research: ******coming soon***
- Contact List of Hospital Operational Directors/Research Directors
- CITI Canada Courses

Research Contacts

Queen's University Research Services & Industry Partnerships

TRAQ Team (general inquires or support)

- traq@queensu.ca
- (613) 533-6000 ext. 78426

Direct Staff Contacts:

http://www.queensu.ca/urs/contact-us

Hospital Research Institutes

KGHRI

- Lisa McAvoy
  - mcavoye1@kgh.kari.net
  - (613) 549-6666 ext. 3344

HDHkRI

- Shari Glustein
  - glustes@hdh.kari.net
  - (613) 544-3400 ext. 2115

PCRI

- Sally Lake
  - lakes@providencecare.ca
  - (613) 548-5567 ext. 5645

N2 CITI Canada Update

New Course: Privacy & Security

(launched May 25, 2016)

If you are a Queen's University Hospital-based Researcher, you and your research staff, students, and trainees can gain access to the free online training through CITI Canada made available by the three hospitals who are members of the Network of Networks (N2). To access the training please contact:

- **KGHRI: Lisa McAvoy:** (mcavoye1@kgh.kari.net or 613-549-6666, ext. 3344)
- **HDHkRI: Shari Glustein** (glustes@hdh.kari.net or 613-544-3400 ext. 2115)
- **PCRI: Sally Lake** (lakes@providencecare.ca or 613-548-5567 ext. 5645)

Additional Courses Available:

- Good Clinical Practice Guidelines Course
- Good Clinical Practice Refresher Course
- Responsible Conduct of Research (RCR) Course-Life Science
- Responsible Conduct of Research (RCR) Course-Physical Science
- The Biomedical Research Ethics Tutorial Course
- The Social and Behavioral Research Course
- Transportation of Dangerous Goods TDG/IATA Course
- Health Canada Division 5 - Drugs For Clinical Trials Involving Human Subjects

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QUESTIONS...