HOSPITAL OPERATIONAL DIRECTORS FREQUENTLY ASKED QUESTIONS (FAQ)

TRAQ DSS FORM: FAQ for HODs Approving Hospital-based Research

How many days do I have to review a TRAQ DSS FORM?



The task flow for processing a TRAQ DSS FORM begins with the Principal Investigator (PI) submitting a TRAQ DSS FORM. For Hospital-based Research, the first step after submission is hospital signing authority approval. Once all Hospital Operational Directors (HODs) and Research Directors (RDs) have signed off on the TRAQ DSS FORM, there are two additional levels of review and approval (i.e. Queen's Head of Department and Faculty Office) required before the TRAQ DSS FORM is forwarded to Queen's University Research Services (URS) for processing. URS will not make a TRAQ DSS FORM "Active" until all necessary certifications (i.e. human ethics, animal care, biohazards), contracts/agreements, and/or funding are in place, if applicable. Queen's Research Accounting will not begin the Peoplesoft/account setup process until receiving authorization from URS.

The PI has been informed that the TRAQ DSS FORM <u>MUST</u> be submitted at least 15 business days in advance of the funding agency deadline to ensure all of their hospital and other approvals are in place prior to submission. It has also been recommended to PIs that they consult with HODs and RDs 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 certain sections for a human ethics review submission, etc.

HODs and RDs are encouraged to view TRAQ DSS FORMs promptly when they first arrive in their Researcher Portal to determine if they have the information required to make a decision regarding a TRAQ DSS FORM. The 15 business days allows time for you to request any missing documents from the PI required to assess the impact, if any, to your department and make a decision. The time window also provides the PI time to respond should you have questions or concerns that must be addressed and finalized before approval can be given. Please note that many funding applications are time-sensitive with fixed deadlines and so your prompt attention to your TRAQ DSS FORMs is much appreciated.

How do I access a TRAQ DSS FORM to review it?

TRAQ DSS FORMs that have been submitted by PIs are accessed through the Researcher's Portal.

HODs and RDs with a Queen's email address (Queen's Faculty & Staff) should use their regular Queen's NetID and









password to log into the Researcher's Portal through the Single Sign On or through MyQueensU/SOLUS portal: http://www.queensu.ca/traq/signon.html.

HODs and RDs (external users with KHSC (KGH, HDH) and PC email addresses) will log into the Researcher's Portal through the Post-Registration Login Site using their full email address as their username and the password that was created during registration: https://eservices.queensu.ca/ROMEO.Researcher.Admin/. Alternatively, you can click on the link in the email that you receive letting you know that a new TRAQ DSS FORM is in your queue. This will take you directly to the Researcher's Portal for you to log into the TRAQ system.

Once logged into the Researcher's Portal, HODs and RDs will have at minimum three roles on their homepage visible: Principal Investigator, Project Team Member, and Custom Signing Authority. Any TRAQ DSS FORM awaiting your approval will be available under Role: Custom Signing Authority. Click on Applications (New – for Review) to access any TRAQ DSS FORM awaiting your review and approval. Then, click on View to review the contents of the TRAQ DSS FORM that you want to look at. If you want to go back and look at any TRAQ DSS FORMs that you have previously approved, click on Applications (Submitted – Post Review) under Role: Custom Signing Authority and choose the project that you want to review.

You will receive an email notification whenever there is a new TRAQ DSS FORM awaiting your review. You will also receive a reminder email on Monday mornings drawing your attention to any TRAQ DSS FORMs still pending your review and approval in your queue.

What do I do if the PI hasn't attached the documents I need to approve the TRAQ DSS FORM?

PIs have been informed that HODs and RDs <u>DO NOT</u> 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. PIs <u>MUST</u> include the necessary documents and attach the files to their TRAQ DSS FORM under the "**Attachments**" Tab. These documents are required before <u>ANY</u> HOD and/or RD can sign-off. The combination of supporting documents and the revised Hospital Departmental Impact and Information Form attached to a TRAQ DSS FORM should help to expedite the hospital review process. Recently we created tips sheets and held educational sessions for the research community to assist them with understanding the requirements for Hospital-based Research.

If the PI hasn't attached the documents required (i.e. research proposal/study protocol, budget/budget justification (if applicable), Hospital Departmental Impact & Information Form, KHSC Pharmacy Services Study Request Form (if applicable), KHSC Laboratory Services Study Request Form (if applicable), KHSC Clinical Engineering Services Study Request Form (if applicable)) to their TRAQ DSS FORM, please email or telephone directly the PI and/or one of their research team members (contact info in Project Team Info tab) and cc Lisa McAvoy (Hospital TRAQ Administrator for KHSC (KGH and HDH Sites) and PC; Lisa.McAvoy@kingstonhsc.ca) requesting the information you need. The PI or one of the research team members can email you the required documents. If you telephone directly, please note this in the comment section indicating that "you have spoken directly with the PI or research team member (please specify date if you can) and indicate that you are satisfied with the information provided in that discussion". You can also document in the comment section any conditions for approval.

IMPORTANT:

By copying Lisa on the email you send the PI or their research team member, she can eventually upload the documents









to the TRAQ DSS FORM or push the application back for the PI to attach the documents to the TRAQ DSS FORM after you have hit the "Approve" or "Forward" button. However, Lisa <u>CANNOT</u> push the TRAQ DSS FORM back to the PI to add all the missing documents to have a complete TRAQ DSS FORM on file until all HODs/RDs and the Department Head have approved the TRAQ DSS FORM. If you want your approval documented, you need to reach out to the PI/research team for the necessary documents. If you hit the "Forward" button and add a comment "cannot approve as documents missing", the TRAQ DSS FORM <u>cannot</u> be resent back to you to re-approve once the PI adds the documents to the TRAQ DSS FORM.

What should I do if I notice that the appropriate Hospital Operational Directors and/or Research Directors have not been selected in the "Approvals Tab" after I have reviewed all the documents and ready to make my decision?

If the PI has <u>NOT</u> selected the appropriate HODs and RDs in the Approvals Tab, please note this comment in the comment section before you hit the "Approve" or "Forward" button. When Lisa (wearing her Faculty Signing Authority hat) reviews the TRAQ DSS FORM she will read your comments and she can push the TRAQ DSS FORM back to the PI to add additional HODs and/or RDs to the TRAQ DSS FORM for approvals.

What should I do if I'm going to be away for an extended period of time (vacation, medical leave, etc.)?

If you plan on being away for an extended period of time due to vacation, medical/parental leave, etc., please notify the following people so that a signing delegate may be temporarily added to the TRAQ system to continue to approve TRAQ DSS FORMs during your absence:

• All HODs: TRAQ: traq@queensu.ca

PLUS

• KHSC- Research Director: Dr. Steven Smith sps1@queensu.ca

• PC Research Director: Allison Philpot philpota@providencecare.ca

Some hospital departments already have in place a secondary HOD who can "review only" TRAQ DSS FORMs. The secondary HOD cannot approve a TRAQ DSS FORM in the system. During your absence this secondary HOD can have their role temporarily changed to "primary HOD" so that they can review and approve TRAQ DSS FORMs and your role will be switched to a secondary HOD during your absence. The roles can easily be reversed upon your return. Any hospital department can add a regular secondary HOD to their profile but it will require that this secondary HOD obtain a username and password and undergo a quick tutorial of the TRAQ system. Please be assured that the TRAQ team or Hospital research facilitators will not add a secondary HOD to any hospital department without your permission.

How do I document discussions I have had with the PI related to a research project?

If you have communicated via email, telephone or in person with the PI, you can document conversations and conditions related to an approval in the comments section of the TRAQ DSS FORM before you hit the "Approve" or "Forward" button. You can also "copy and paste" any emails received into the comments section. If the original documents were not attached to the TRAQ DSS FORM, you can also add a comment indicating that "you have reviewed"









the required documents sent to you by email and that based on the information sent to you, you "Approve" or "Conditionally Approve" or "Do Not Approve" the TRAQ DSS FORM".

When do I hit the "Approve" button versus "Forward" button?

The "Approve" button is selected when you are satisfied with the documents received and any conversations you may have had with the PI offline related to the research project and you are ready to approve the TRAQ DSS FORM. Some HODs/RDs prefer using the "Forward" button when they conditionally approve a TRAQ DSS FORM. This is okay. If you do not approve a TRAQ DSS FORM, please use the "Forward" button and include a rationale in the comment section.

The TRAQ DSS FORM does not have the required certifications in place: can I indicate my approval is conditional until the certification approval is obtained?

Yes: you can include a comment on the Approvals Tab that "approval is conditional upon all required certifications being in place". Any required certification(s) are to be noted in TRAQ DSS FORM Question 4.6 and any pending or approved certification numbers are to be linked to the TRAQ DSS FORM by the PI. All required certifications (i.e. human ethics, animal care, biohazards) must be in place before research can commence or and research account can be opened. There are systems in place at the Hospital and University level to ensure that PIs have all the necessary approvals in place before being given the green light to commence the project.

After you have made a decision related to any TRAQ DSS FORM by hitting the "Approve" or "Forward" button, you can go back into the TRAQ system and look up any TRAQ DSS FORM. Click on **Applications (Submitted – Post Review)** under Role: Custom Signing Authority and search for the research project. Once certifications are in place for a particular research project, the TRAQ DSS FORM is automatically updated and you can see the expiry dates and approval letters attached for these certifications. **Please do not wait to approve a TRAQ DSS FORM until all certifications are in place.** The corresponding certification committees are in place to take care of this for any research project.

What should I do if I need more time to review (more than 15 days)?

If you need more time and there is an Agreement attached and there is some urgency to having it reviewed in parallel, you can Forward the application indicating that you have not yet approved and need more clarification/time before you can Approve it. A Milestone "Waiting for Final HOD Approval" will be created and it will be back in your queue to review further.

Which web browsers is TRAQ compatible with?

The TRAQ system 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. The Researcher's Portal is accessible on most tablets (i.e. iPads, Playbooks, etc.).

Need Help?

For questions regarding Hospital-based Research, please contact:









- Kingston General Health Research Institute-KGH/HDH Site:
 Lisa McAvoy, 613-549-6666 ext. 3344, <u>Lisa.McAvoy@kingstonhsc.ca</u>
- Kingston General Health Research Institute-KGH/HDH Site:
 Veronica Lloyd, 613-549-6666, ext. 8171, <u>Veronica.Lloyd@kingstonhsc.ca</u>
- Providence Care Research Institute:
 Sally Lake, 613-544-4900 ext. 53494, lakes@providencecare.ca
- 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.

Additional resources available for TRAQ DSS FORMs:

- URS Manuals: http://www.queensu.ca/trag/awards-grants-contracts/manuals
- URS Videos: http://www.queensu.ca/traq/awards-grants-contracts/videos
- Tip Sheets: http://www.kgh.on.ca/research/researchers-staff-trainees







