TRAQ – Human Ethics Module

Health Sciences Research Ethics Board (HSREB)

Applying for HSREB Certification

Researchers' User Manual

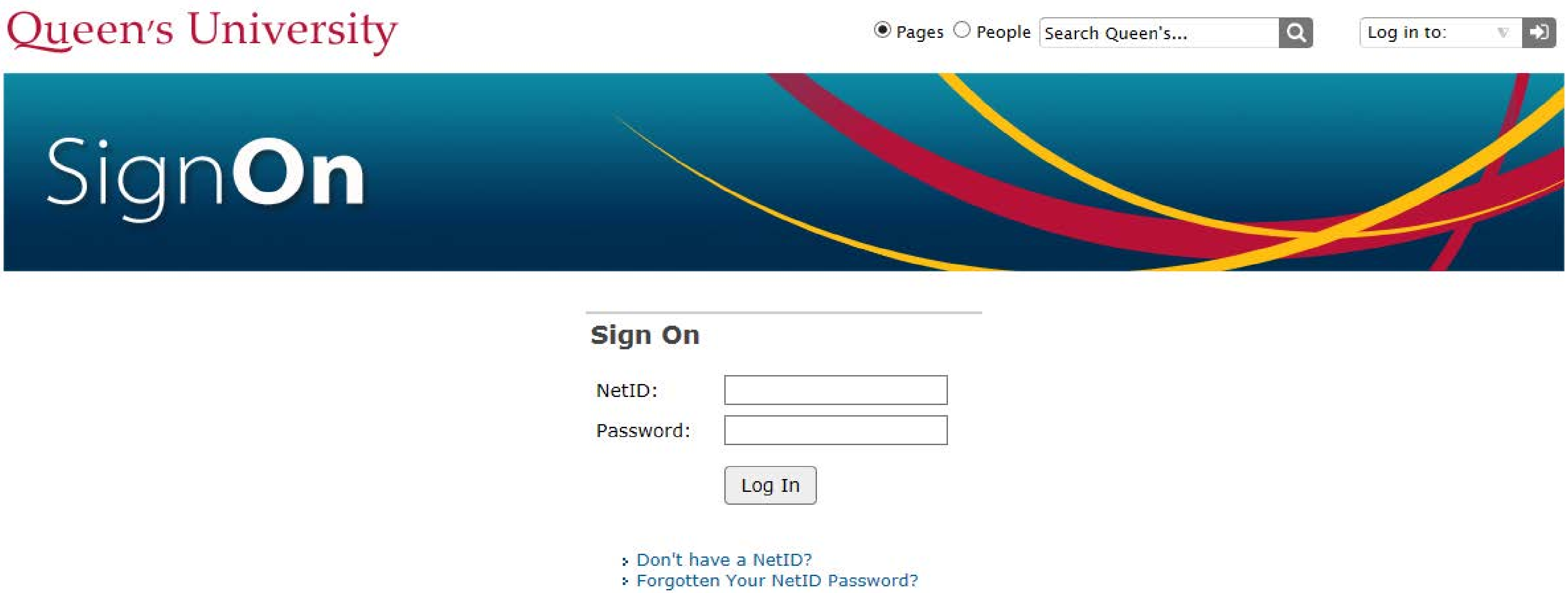
Rev. June 2015

Accessing the TRAQ Researcher Portal

- Queen's faculty and staff should use their regular Queen's NetID and strong password* to log into the TRAQ Researcher Portal through MyQueensU/SOLUS. (Once in MyQueensU, click on My Applications, and then on Go to the TRAQ Researcher Portal hyperlink.)

- The Researcher Portal is also available through the TRAQ website.

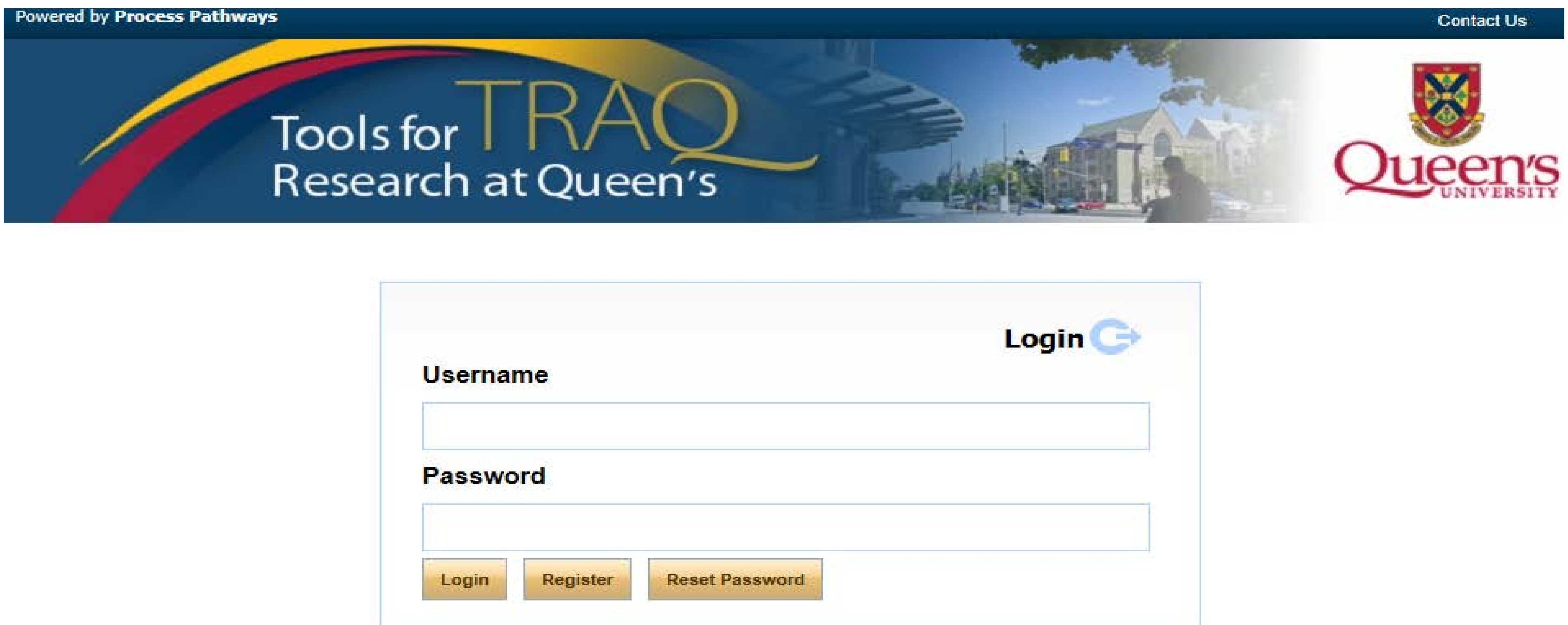
**Information regarding managing your Queen's NetID and strong password is available on the ITS website.*



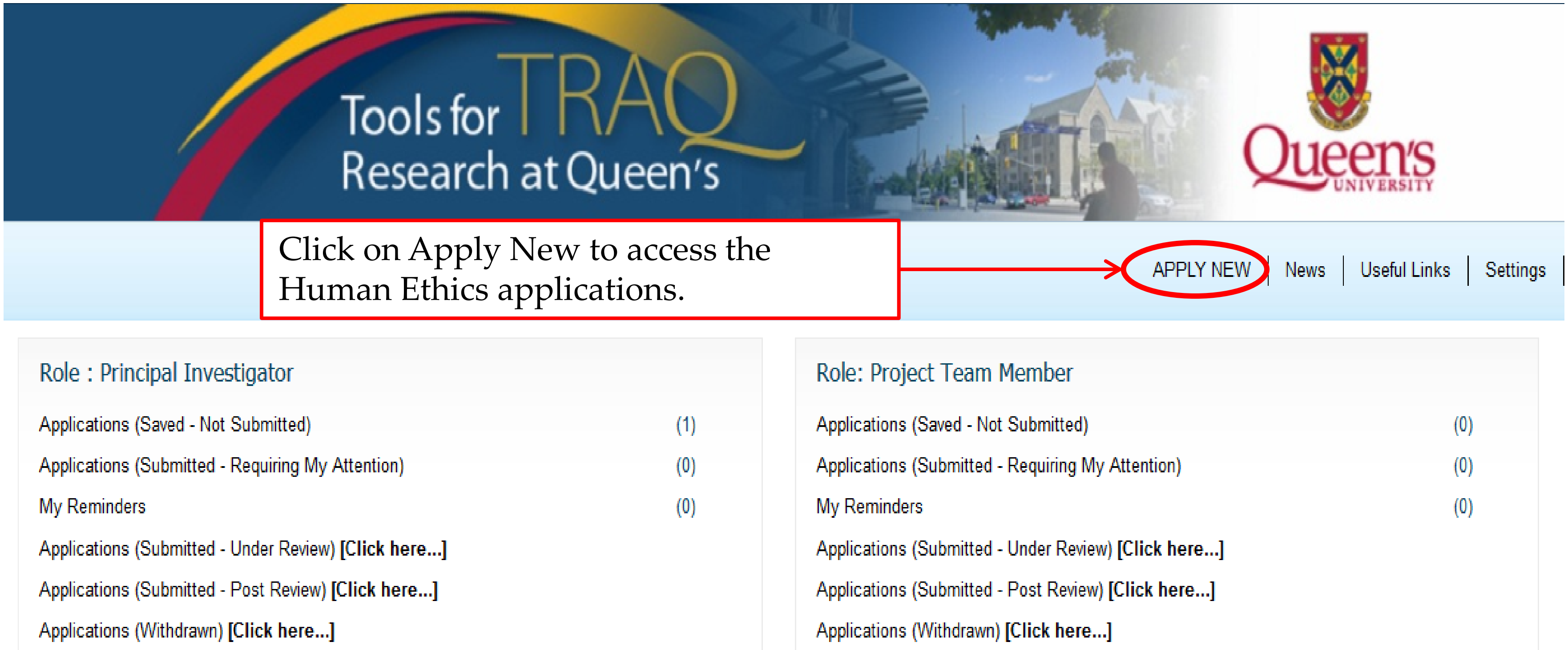
Accessing the Researcher Portal (Cont.)

- Queen's students and external users, trying to log in for the **first time**, will need to complete the Self Registration Form before they can access the Researcher Portal. Once you have registered, you will receive an automatic email with instructions on setting up your own password. From then on, you will access the Researcher Portal through the Post-Registration Login Site.

- When logging in through the Post Registration Login site, your username is the email address provided at the time of registration.



Researcher Portal – Describing the Homepage



Click on Apply New to access the Human Ethics applications.

All users have **Principal Investigator** and **Project Team Member** roles. Depending on your role in a particular study, you will be able to access your files (Human Ethics and Biohazard certifications, and TRAQ DSS Form/Agreement Review applications) under one role or the other.

Starting a New Human Ethics Form

Any research project involving human participants, **whether funded or not**, must receive ethics approval of one of the Ethics Boards prior to the start of the project.

- Non-Health Sciences (Social Sciences) submit to the General Research Ethics Board (GREB)
- Health Sciences and affiliated teaching hospitals submit to Health Sciences Research Ethics Board (HSREB)

New Application Forms

GREB

Application Name	Description	Status
GENERAL RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE (Social Sciences and Humanities)	Updated form - Ja	

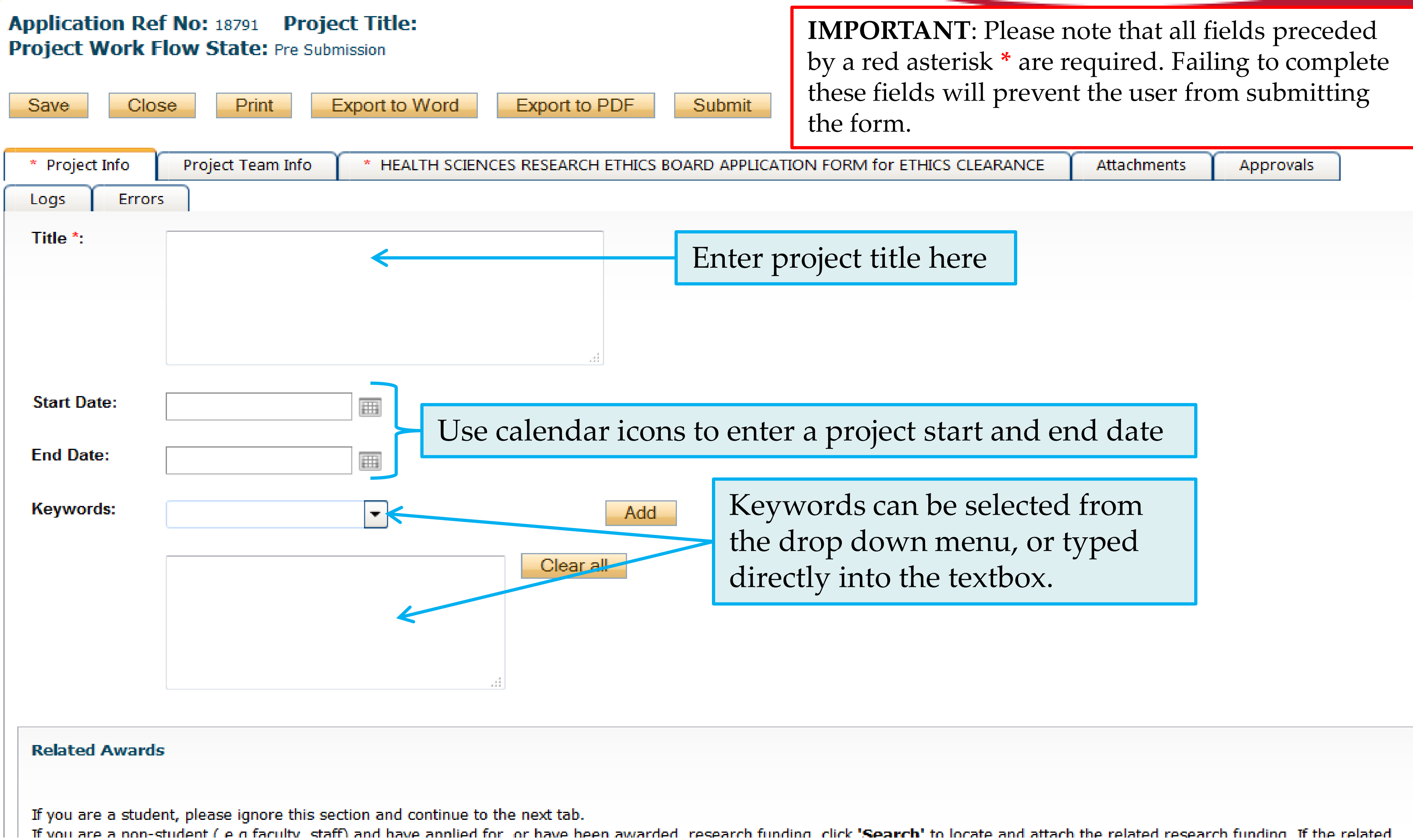
HSREB

Application Name	Description	
HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE	HSREB form - upd	
Health Sciences Research Ethics Board Short Form for Critical Enquiry, Chart reviews, Questionnaires, Surveys	To be used for: chart review, critical enquiry etc.	Open

The names of the forms are hyperlinks, click on them once to open a blank application.

** HSREB applicants must choose between two application forms: the long form and short form for low risk studies. Please contact the Ethics Coordinator of the HSREB if you are unsure which form you should be completing.*

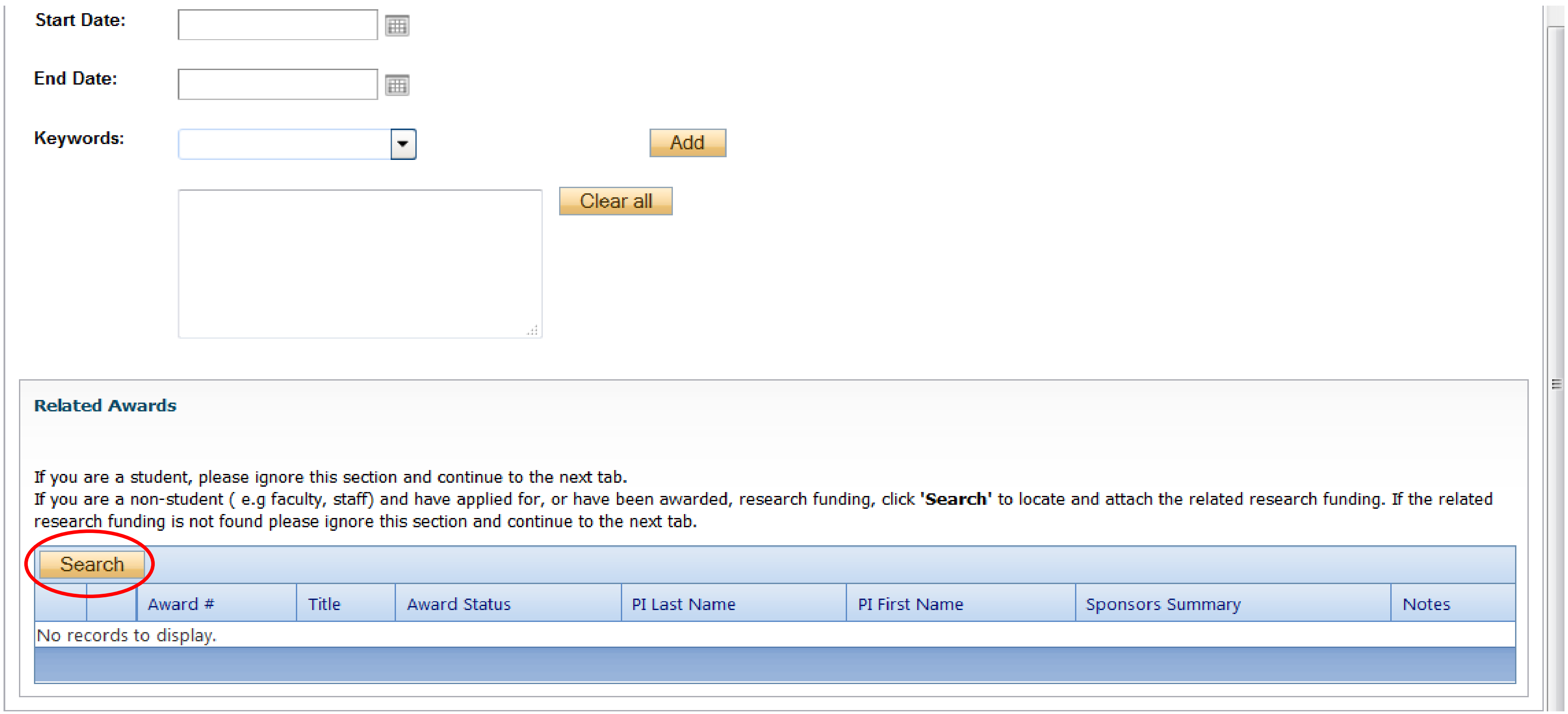
Project Info tab



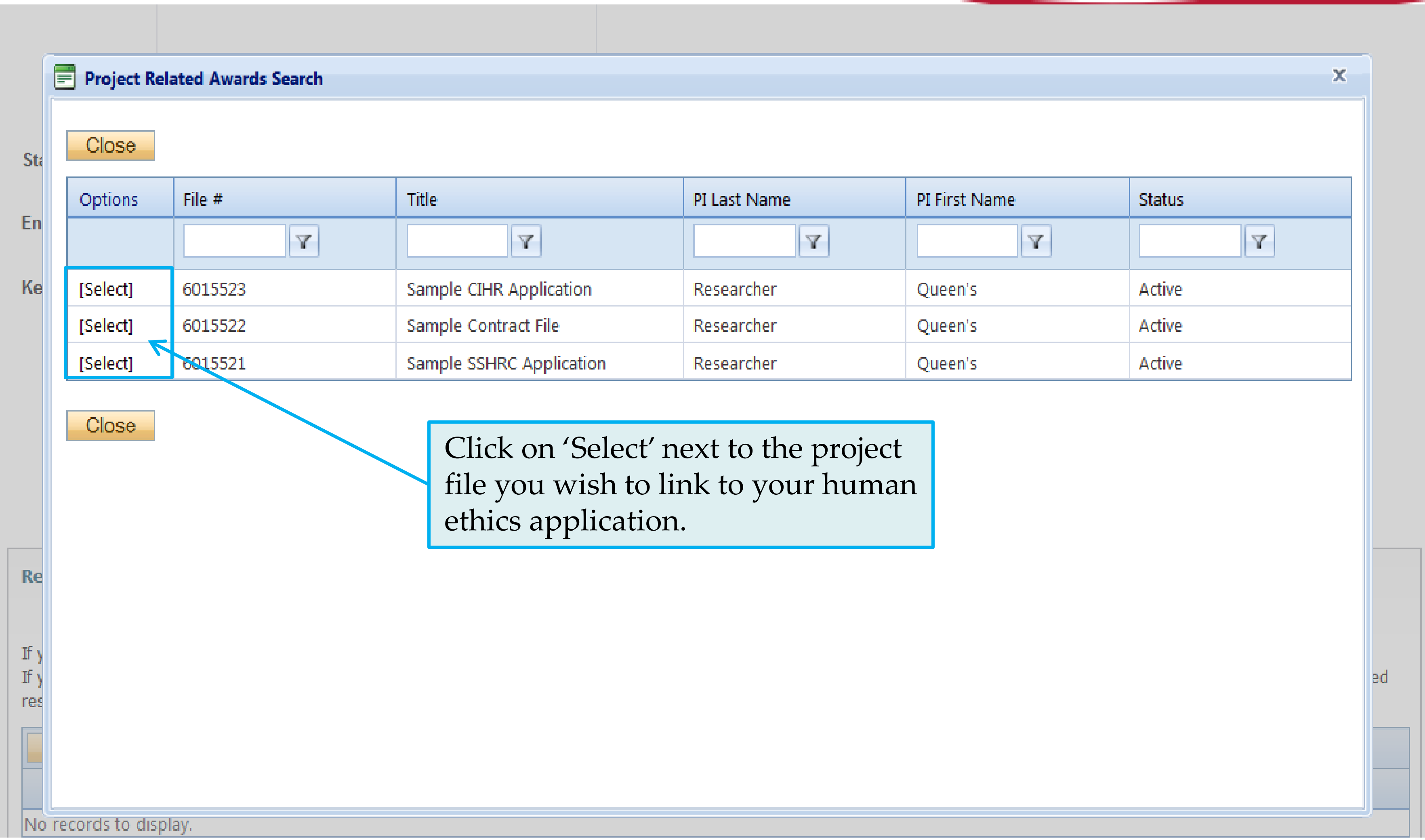
Project Info tab – Related Awards

- If your project is receiving funding, either through a grant or contract, it is important to link your TRAQ DSS Form to your human ethics application.

- Use the side bar to scroll down to the 'Related Awards' section of the Project Info tab screen and click on the yellow 'Search' button to view your submitted TRAQ DSS Forms.



Project Info tab – Related Awards (Cont.)

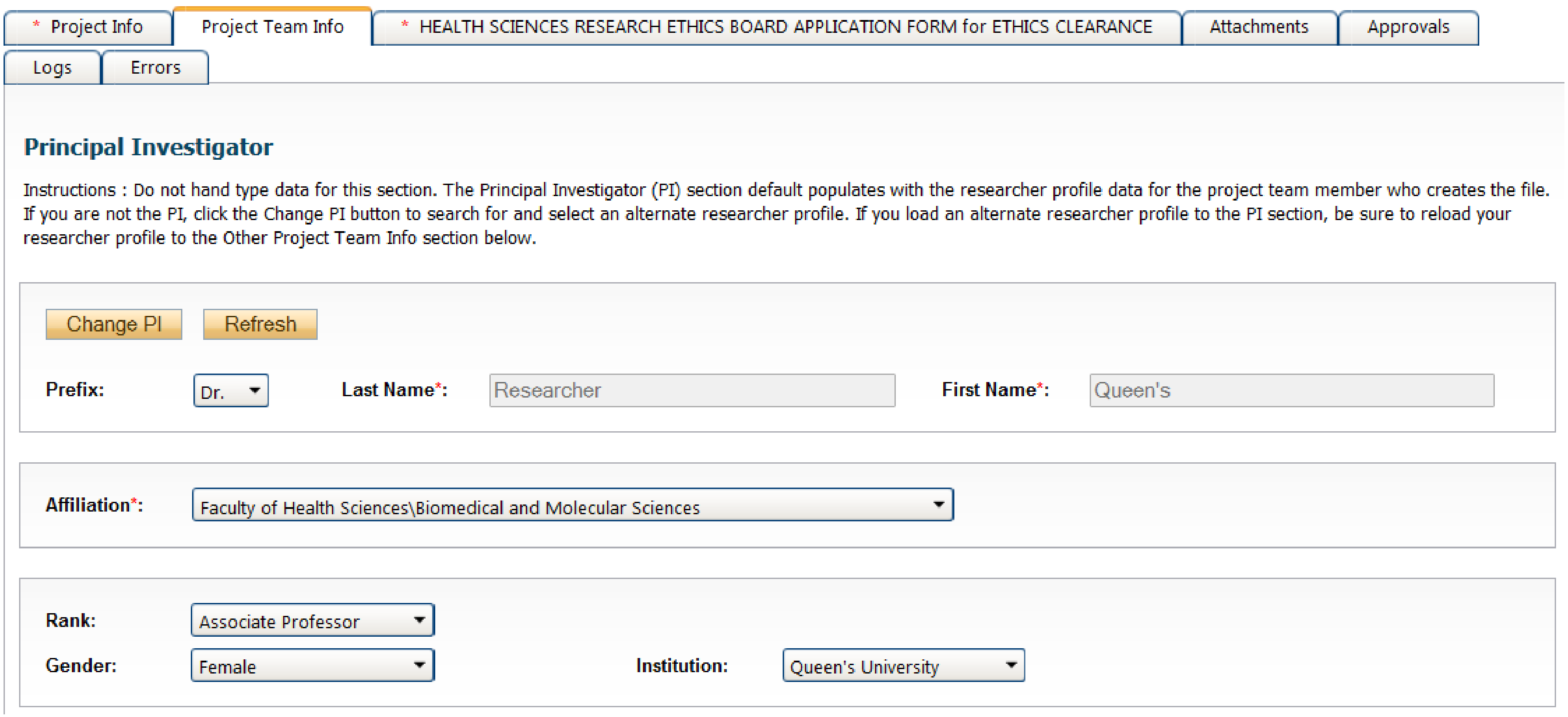


Options	File #	Title	PI Last Name	PI First Name	Status
[Select]	6015523	Sample CIHR Application	Researcher	Queen's	Active
[Select]	6015522	Sample Contract File	Researcher	Queen's	Active
[Select]	6015521	Sample SSHRC Application	Researcher	Queen's	Active

Click on 'Select' next to the project file you wish to link to your human ethics application.

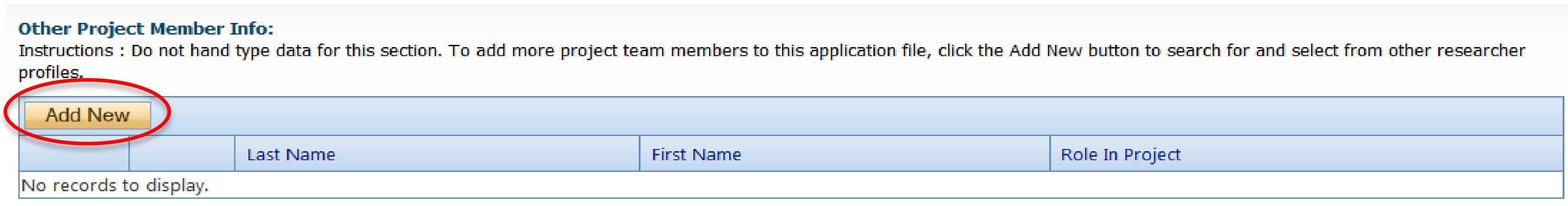
Project Team Info tab

- The top section of the Project Team Info tab (Principal Investigator section) is automatically filled out with the information of the person who created the application. If you are the PI, please continue following the steps outlined in this manual. If you are not the PI, please consult the user manual for Research Coordinators.

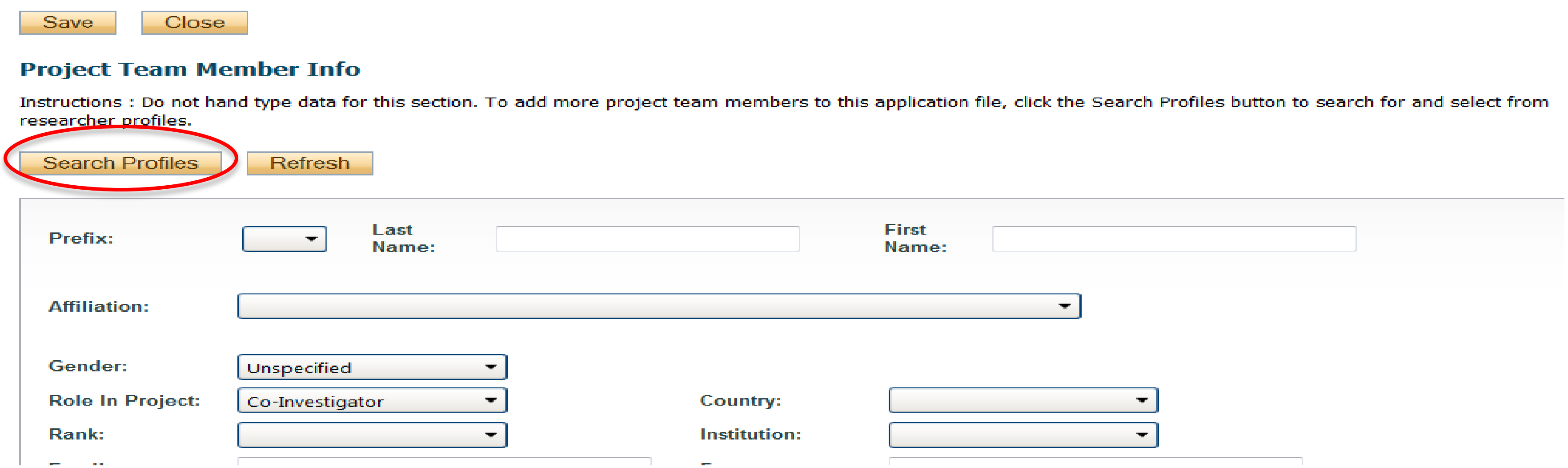


Project Team Info tab - Adding Project Team Members

- From the Project Team Info tab, scroll down to Other Project Member Info and click Add New

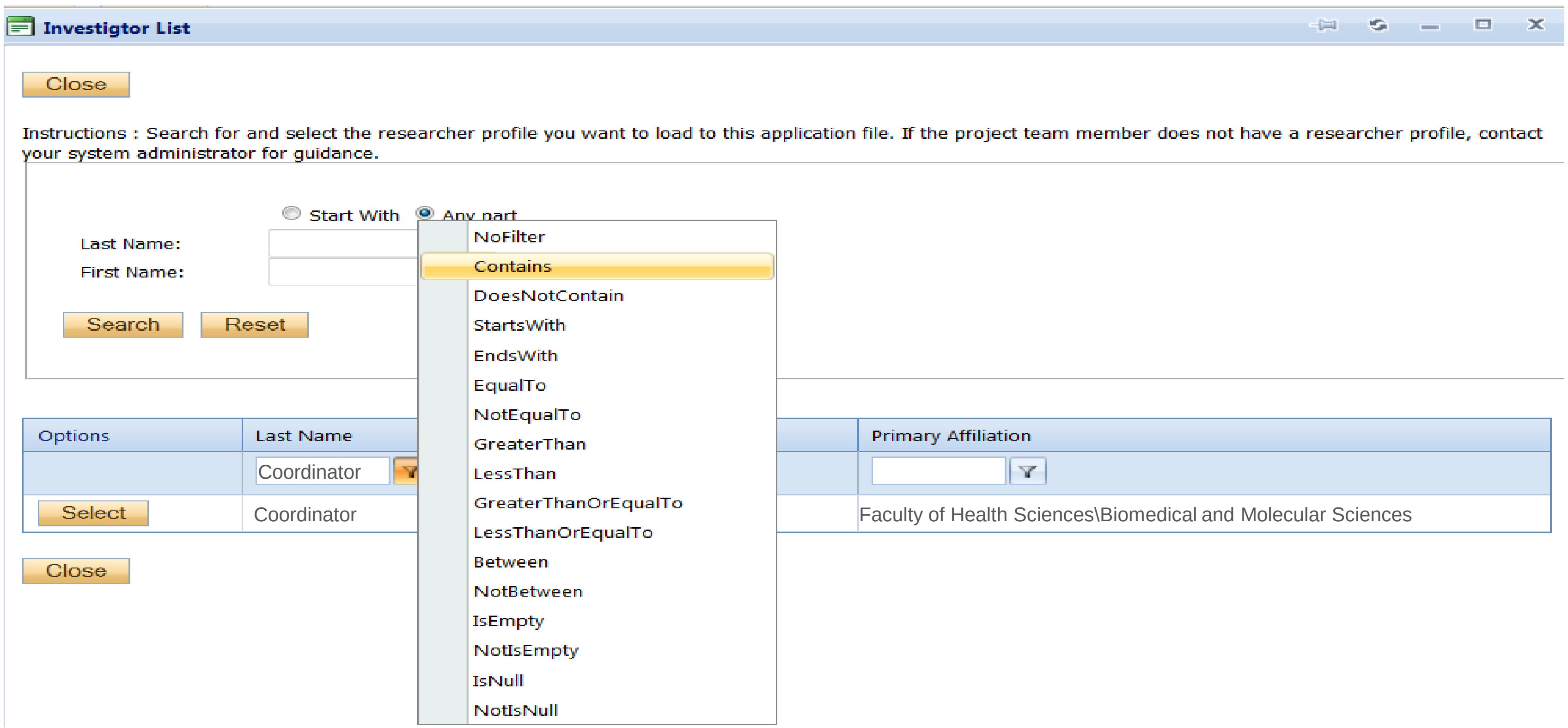


- Click the Search Profiles button to find the person you need to add as team member – **Important: Do not enter this information manually always use 'Search Profiles'**



Project Team Info tab - Adding Project Team Members (Cont.)

- You can search the Investigator List for the name of the person to be assigned as team member. The list can be searched in a variety of ways, i.e. type the last name of the person in the "Last Name" field, use the filter beside it to select a search criteria such as "EqualTo" or "Contains"



Project Team Info tab - Adding Project Team Members (Cont.)

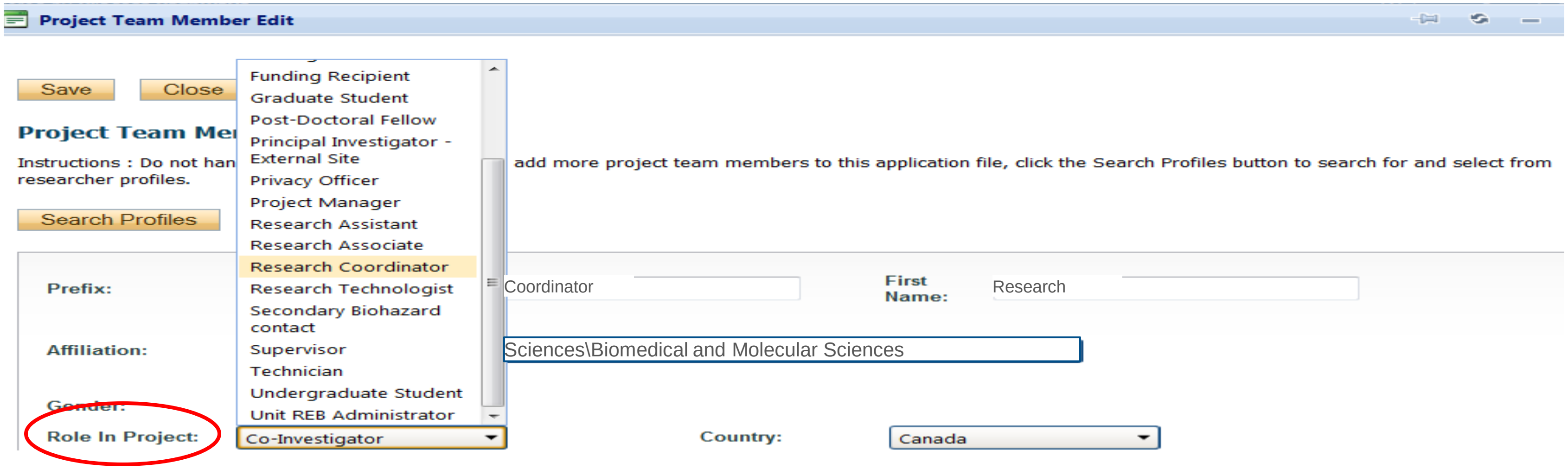
- Once you've identified your team member – click on Select. The project team member form will be updated automatically.

Options	Last Name	First Name	Primary Affiliation
	Coordinator		
Select	Coordinator	Research	Faculty of Health Sciences\Biomedical and Molecular Sciences

- If you are unable to identify the person you are looking for from the investigators list, please email the TRAQ helpdesk (traq@queensu.ca). Your email should include the person's full name, title, business address and email address. You will be notified as soon as the person has been added to the investigators list and will then be able to add them to the project team.

Project Team Info tab - Adding Project Team Members (Cont.)

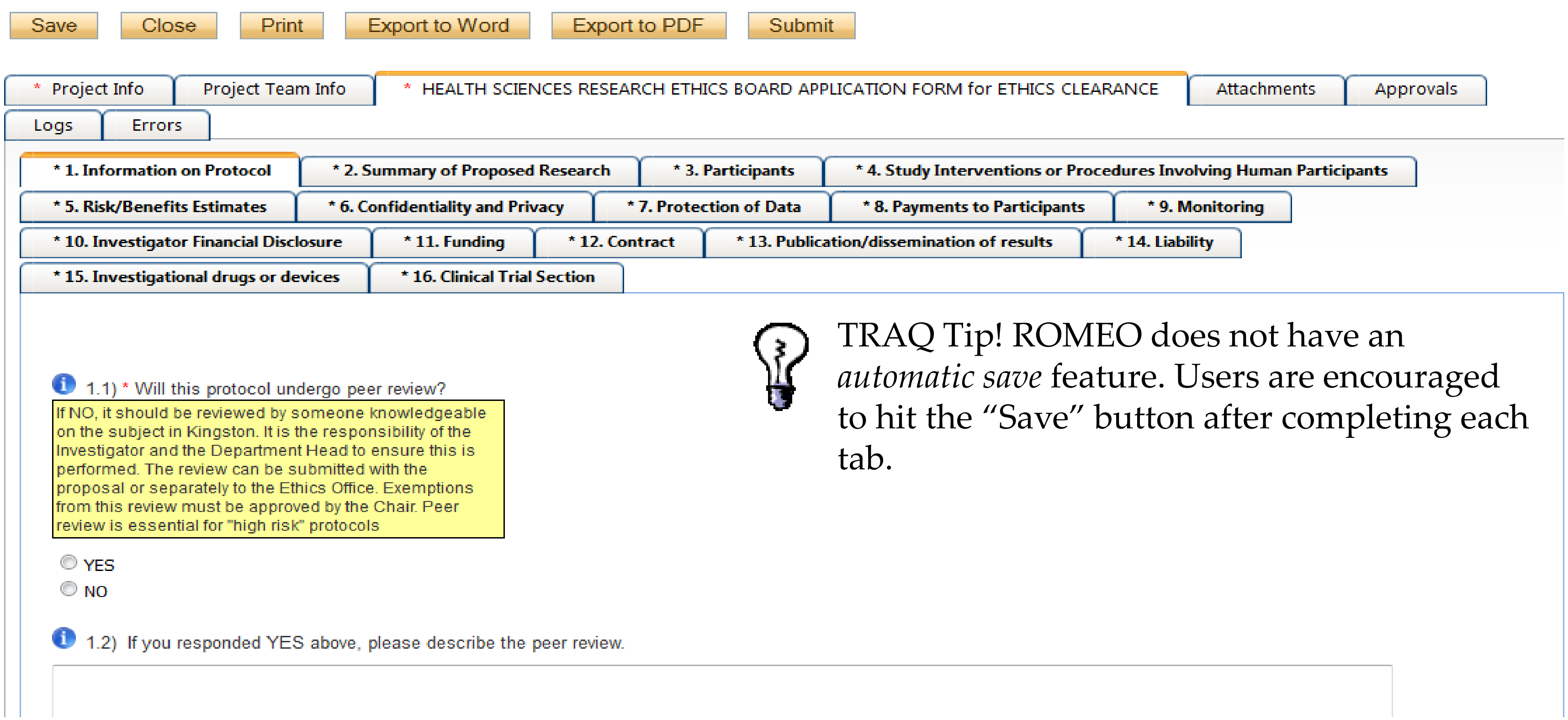
- From there, you may select the role of the team member from the 'Role In Project' drop down menu **(Important: Student applicants should always assign their supervisor(s) as team members and select "supervisor" role)**



- You may add as many team members as required by clicking 'Add New', team members can also be edited or deleted. Keep in mind that anyone who will need to have access to the application should be added as team members. However, only the P.I., the Supervisor and the Research Coordinator will be copied on all system generated email correspondence. It is therefore recommended that Research Administrators assign themselves to the Research Coordinator role.
- **Important: Although all team members will have access to view and edit the application, the P.I. is the only member of the project team who can submit the application once it is ready to be reviewed.**

Health Sciences Research Ethics Board Application Form tab

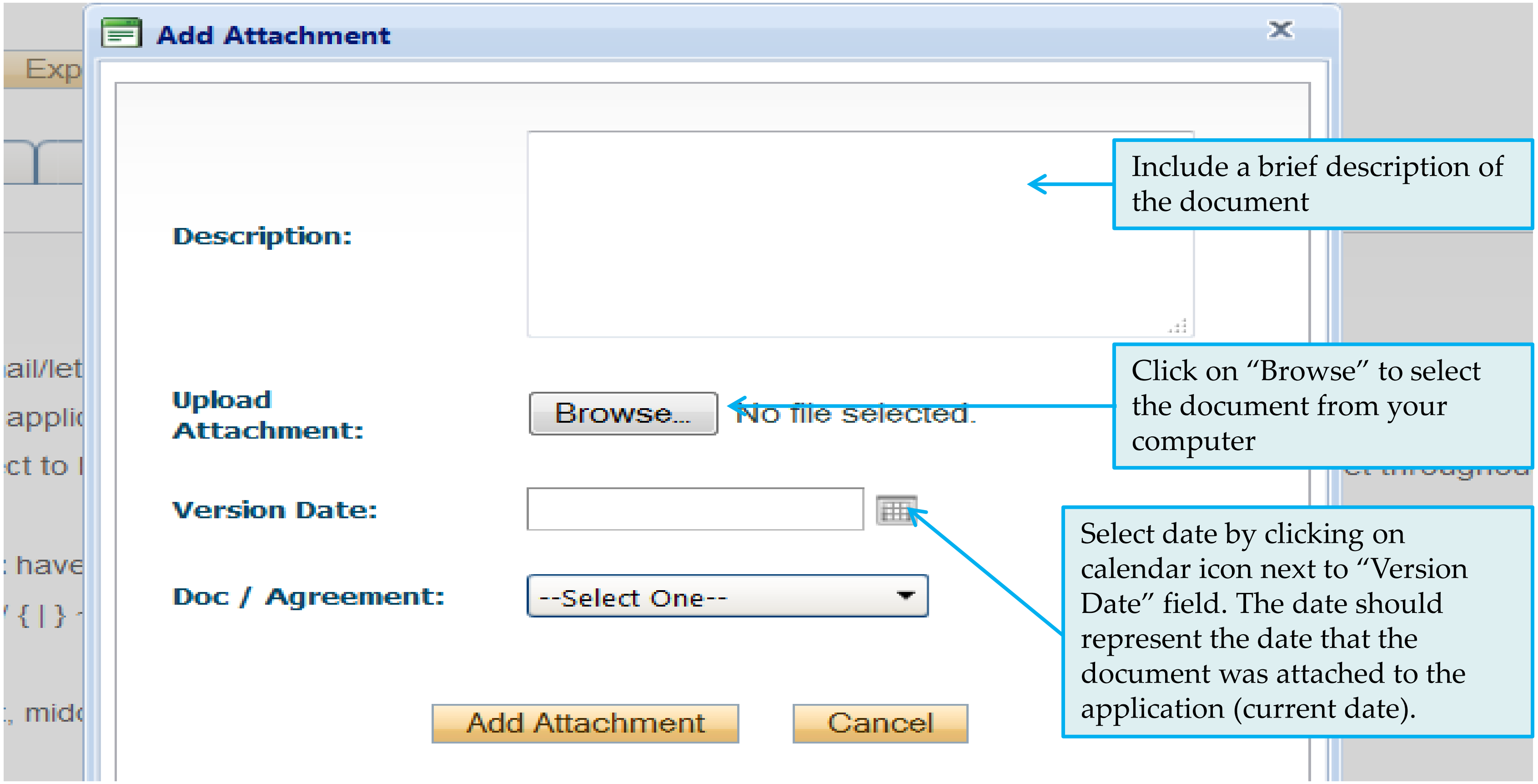
- This tab has several sub-tabs all of which contain required questions. If you are unsure how to answer a question, try clicking on the info tab (i) additional information may be available as seen in the screenshot below!



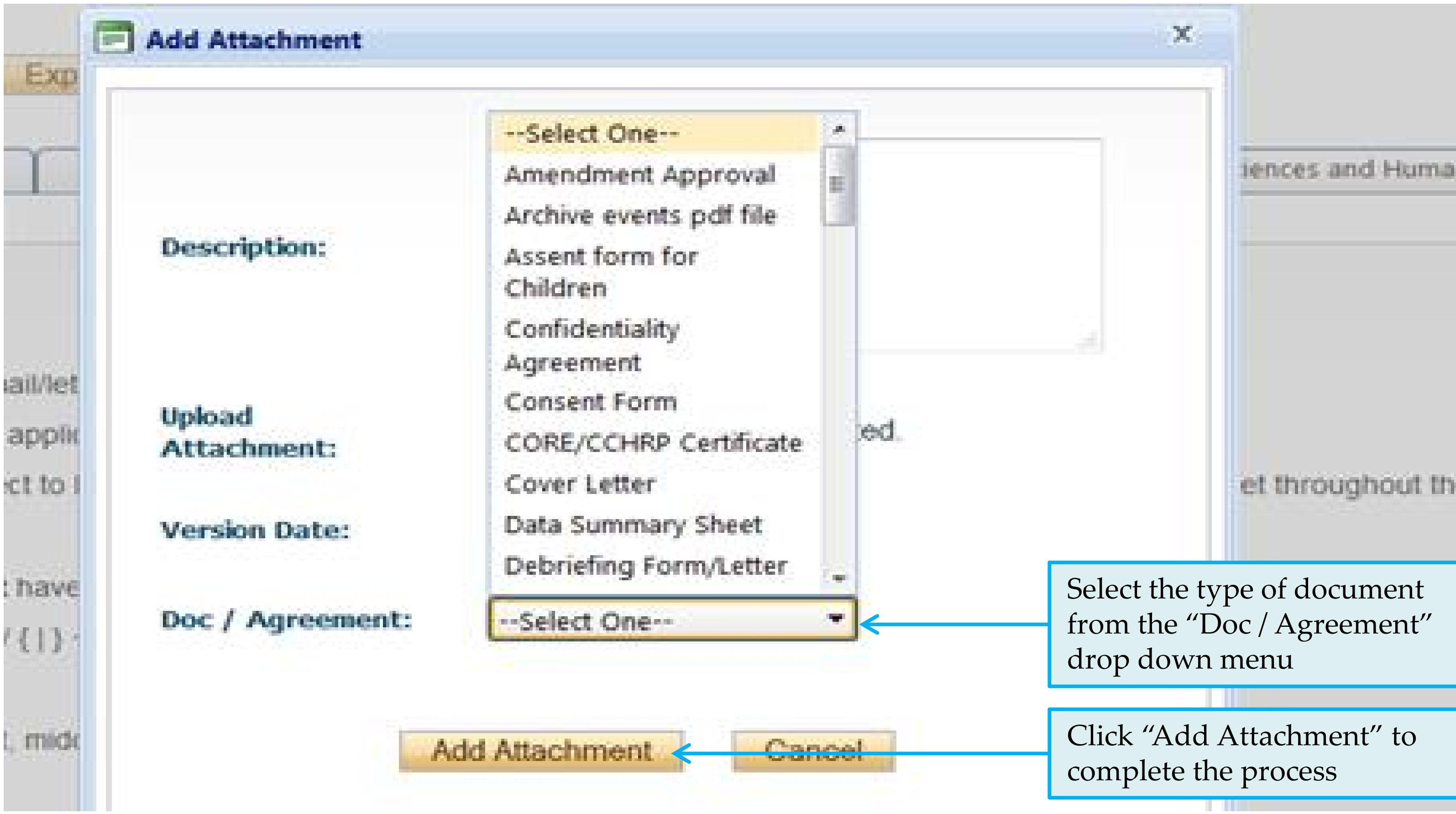
TRAQ Tip! ROMEO does not have an *automatic save* feature. Users are encouraged to hit the “Save” button after completing each tab.

Attachments tab

- Applicant should attach any document(s) identified on the Checklist sub-tab of the Ethics Form. Users may upload multiple attachments, provided that each is no larger than 5MB. Attachments may be word files, spreadsheets, jpeg files, pdfs, etc.



Attachments tab (Cont.)



Select the type of document from the "Doc / Agreement" drop down menu

Click "Add Attachment" to complete the process

Approvals tab

- The Approvals tab simply describes the workflow of an application in TRAQ. For example, this HSREB application will be submitted straight to the HSREB (Office of Research Services/Office of Research Ethics). This workflow is pre-determined. You may skip this tab.

Application Ref No: 18791 **Project Title:**
Project Work Flow State: Pre Submission

Application Form: HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE

Save | Close | Print | Export to Word | Export to PDF | Submit

* Project Info | Project Team Info | * HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE | Attachments | Approvals
Logs | Errors

Approvals

This application is pre-programmed to route to the following signing authority levels

Role	Active	Exceptions
Division Signing Authority	☐	
Department Signing Authority	☐	
Faculty Signing Authority	☐	
Office of Research Services/Office of Research Ethics	☑	

Logs tab – Workflow Logs

- The Logs tab is a useful tool that allows the applicant(s), reviewer(s) and the Ethics Office to track the history of the application and communicate with one another. Text in blue font represents most recent updates

- The Workflow Logs tracks and time stamps approvals and messages

Save | Close | Print | Export to Word | Export to PDF | Submit

* Project Info | Project Team Info | * HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE | Attachments | Approvals

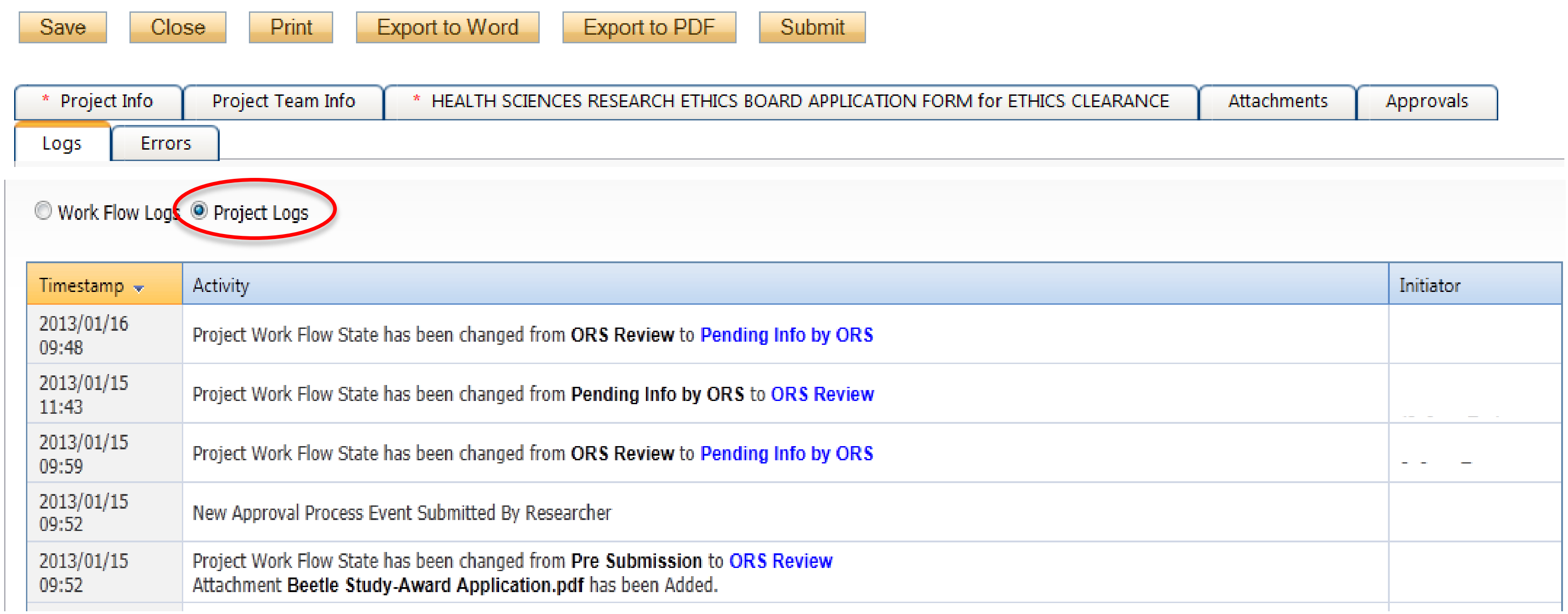
Logs | Errors

Work Flow Logs | Project Logs

Timestamp	Log	Work Flow State	Message	User	Role/Group
16/01/2013 09:48	Project Work Flow State has been changed from **ORS Review** to **Pending Info by ORS**	**ORS Review** -> **Pending Info by ORS**	Consent Form still missing.		Office of Research Ethics
15/01/2013 11:43	Project Work Flow State has been changed from **Pending Info by ORS** to **ORS Review**	**Pending Info by ORS** -> **ORS Review**	Changes made as requested [Action: Re-Submit]		Principal Investigator
15/01/2013 09:59	Project Work Flow State has been changed from **ORS Review** to **Pending Info by ORS**	**ORS Review** -> **Pending Info by ORS**	Dear Dr Gagnon & Dr Herra, Your application went through review board - reviewer requires clarification from researcher. Revised consent form needed. Jan. 15, 2013 Please submit revisions within 2 business days. Regards, Kathy		Office of Research Ethics

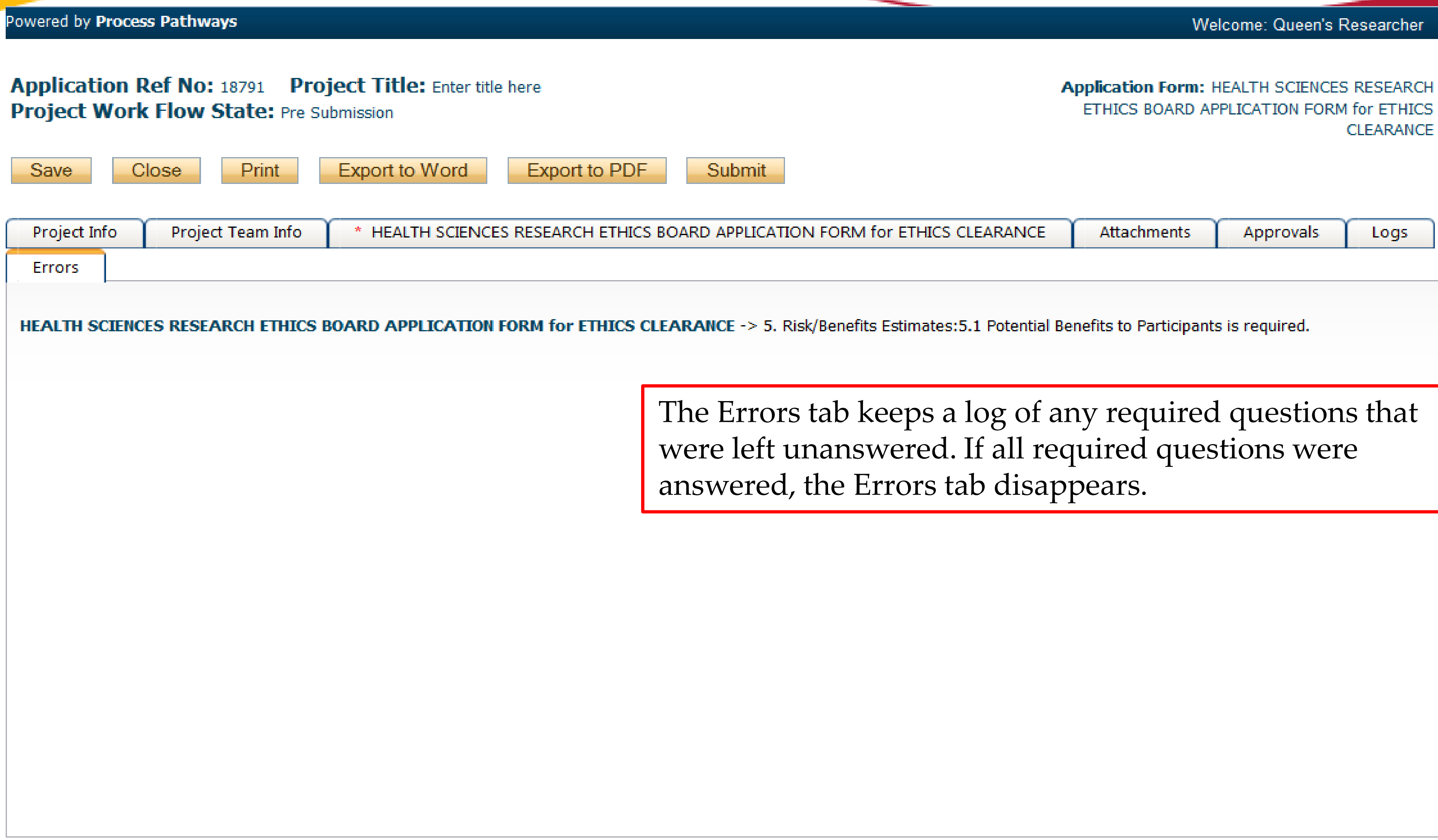
Logs tab – Project Logs

- The Project Logs tracks and time stamps every action taken on the application.



Timestamp	Activity	Initiator
2013/01/16 09:48	Project Work Flow State has been changed from **ORS Review** to Pending Info by ORS	
2013/01/15 11:43	Project Work Flow State has been changed from **Pending Info by ORS** to ORS Review	
2013/01/15 09:59	Project Work Flow State has been changed from **ORS Review** to Pending Info by ORS	
2013/01/15 09:52	New Approval Process Event Submitted By Researcher	
2013/01/15 09:52	Project Work Flow State has been changed from **Pre Submission** to ORS Review Attachment **Beetle Study-Award Application.pdf** has been Added.	

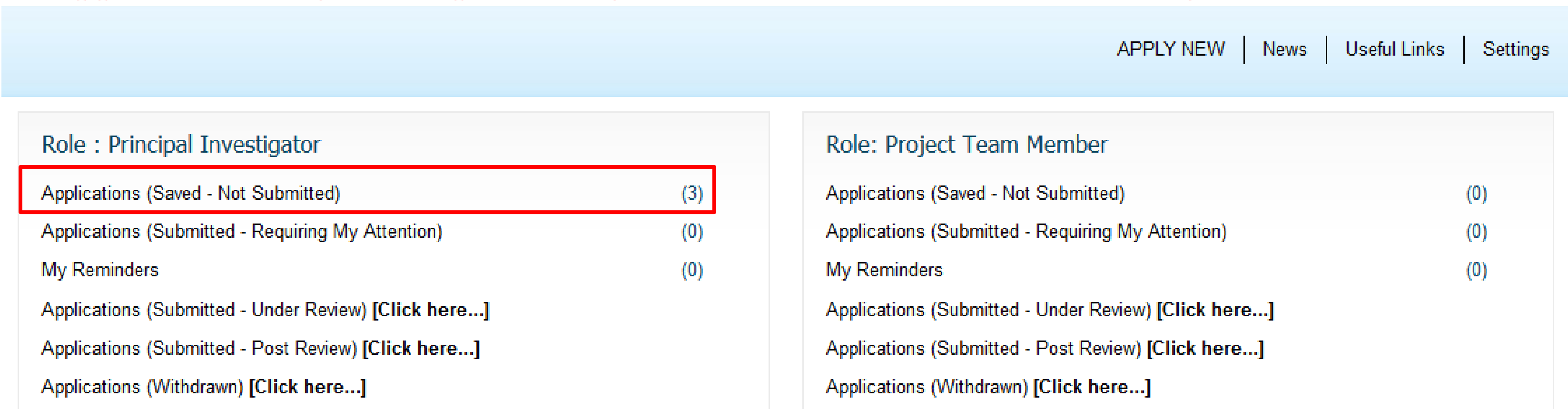
Errors tab



The Errors tab keeps a log of any required questions that were left unanswered. If all required questions were answered, the Errors tab disappears.

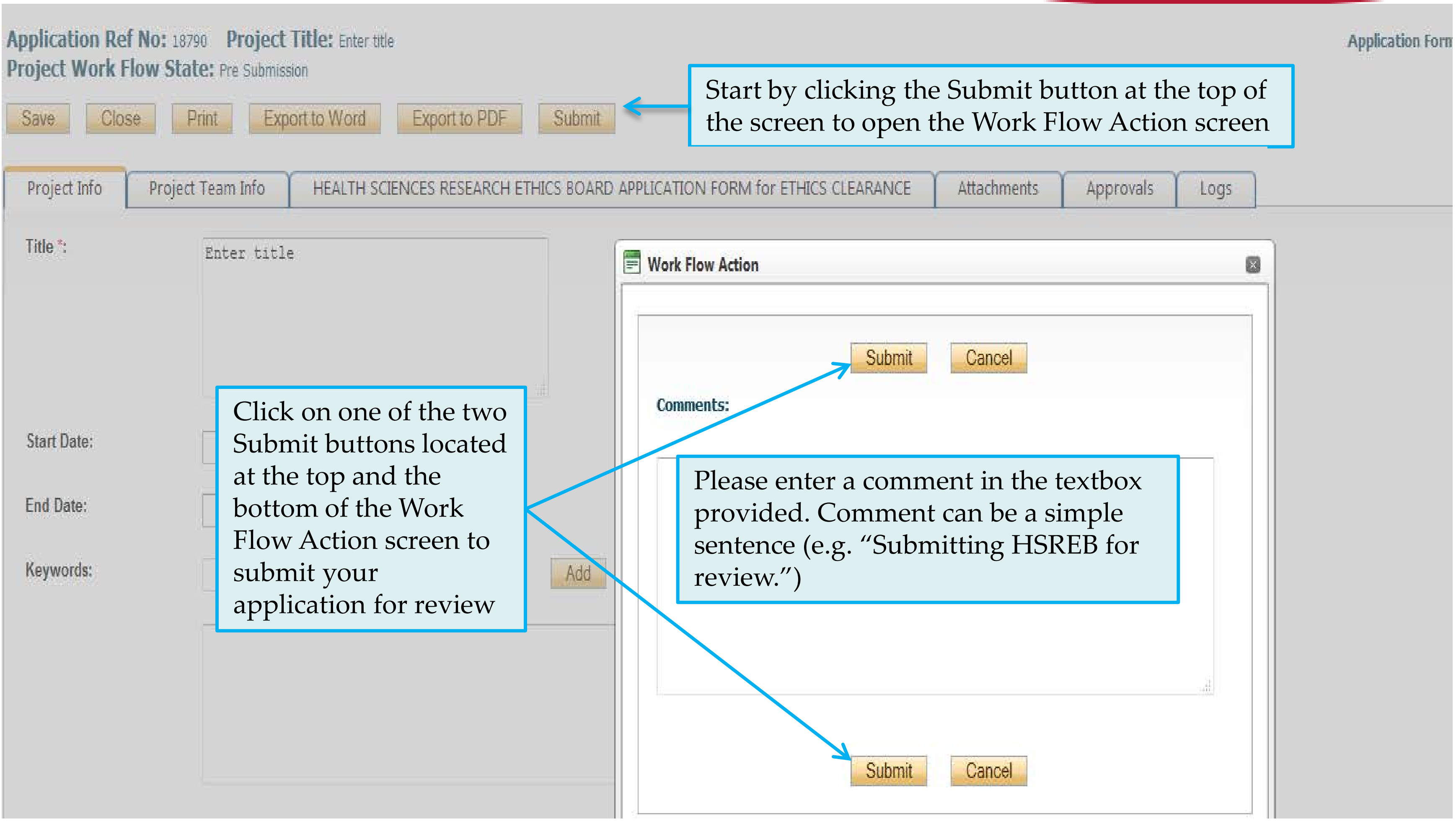
Save and Continue…

- At any point in the process, the applicant may Save and Close the application and complete it at a later date. The information entered will be saved and the user can access it again through the TRAQ Researcher Portal under **Applications (Saved – Not Submitted)**. Important: Do not close that application by clicking the $\boxed{X}$ at the top of your browser, doing so will result in the application being locked preventing other team members from accessing it



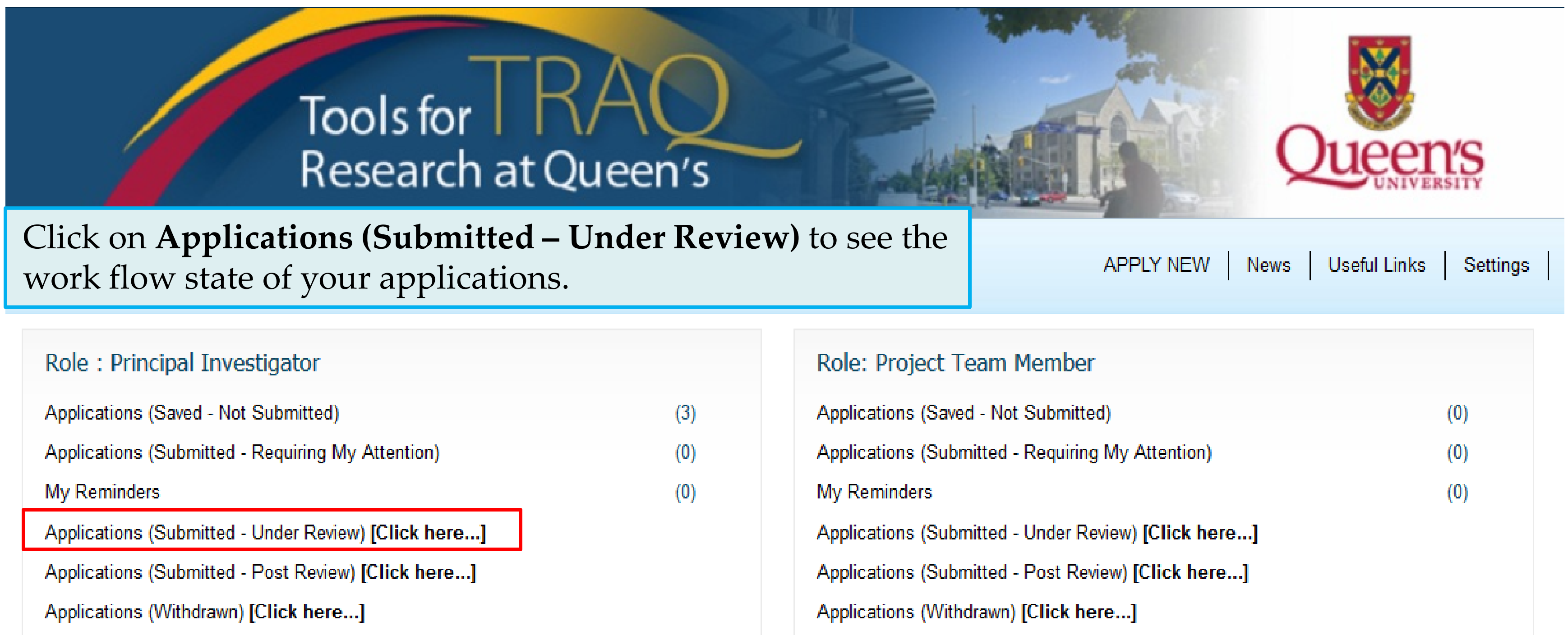
TRAQ Tip! Though ROMEO has no *automatic save* feature, it does have a *time out* feature! If you need to step away from your computer, you should always hit the Save and Close buttons as a precautionary measure. Failing to do so could result in information being lost and the application being locked. The user responsible for locking the application is able to unlock it by accessing it again and exiting properly. All other team members, who find themselves locked out of the application, can either contact the user who locked it or the TRAQ team for support (ext. 78426; email: traq@queensu.ca)

Submitting an HSREB Application



Applications Under Review

- Once you have submitted the application for review, you will receive an email confirming the reception of your application – any team member associated with the application will be copied on the correspondence. At this stage, you will not be allowed to make any changes to the application. However, it is still available for viewing under **Applications (Submitted – Under Review)**



Work Flow State of Applications Under Review

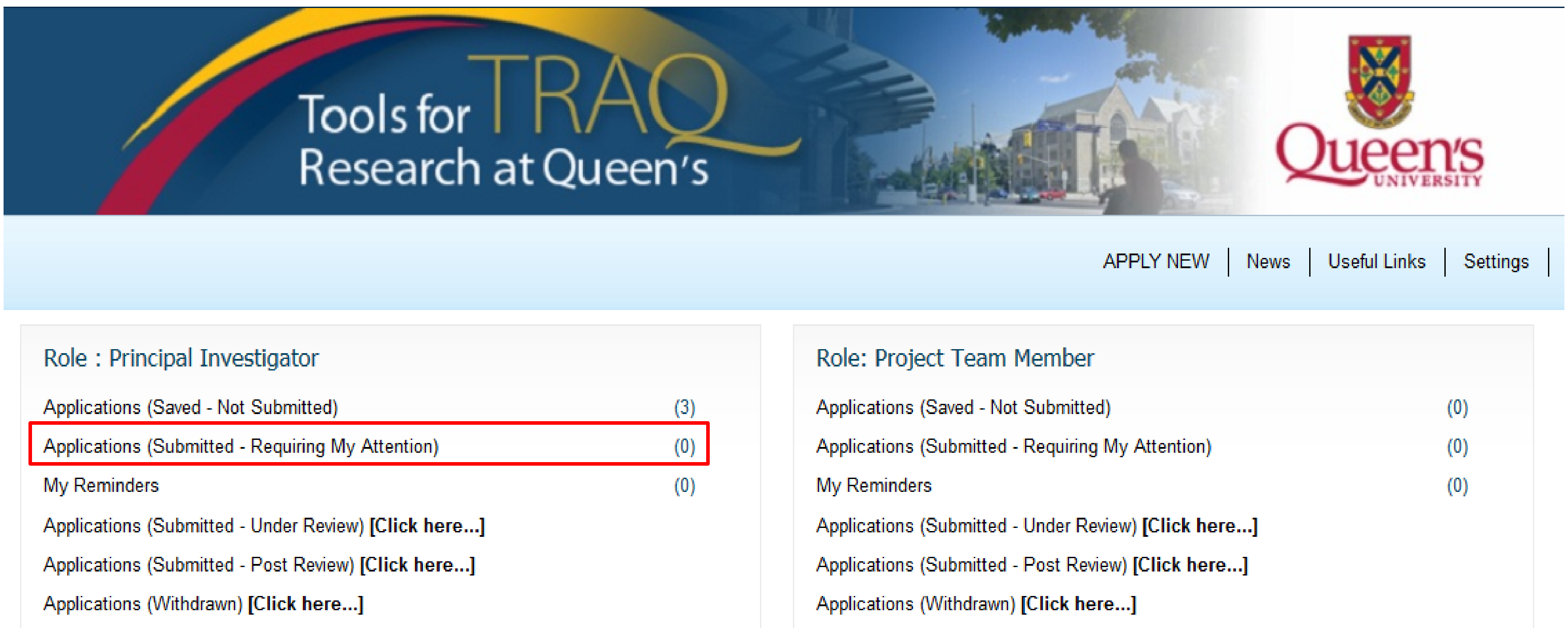
- Check the status of your application(s) under review under the Status Snapshot column.
- In the example below, the HSREB application is pending approval from HSREB (Workflow Status: ORS Review).

Reset Filters | Export To Excel

	File No	Project Title	Principal Investigator	Application Type	Status Snapshot	Workflow Message
				All		
View Clone	**Ref No : 18790**	Enter title	Dr. Queen's Researcher (Faculty of Health Sciences\Biomedical and Molecular Sciences)	HEALTH SCIENCES RESEARCH ETHICS BOARD APPLICATION FORM for ETHICS CLEARANCE (Certification\Human Ethics)	**Project Status:** Pending **Workflow Status:** ORS Review	Please review [Action: Submit]

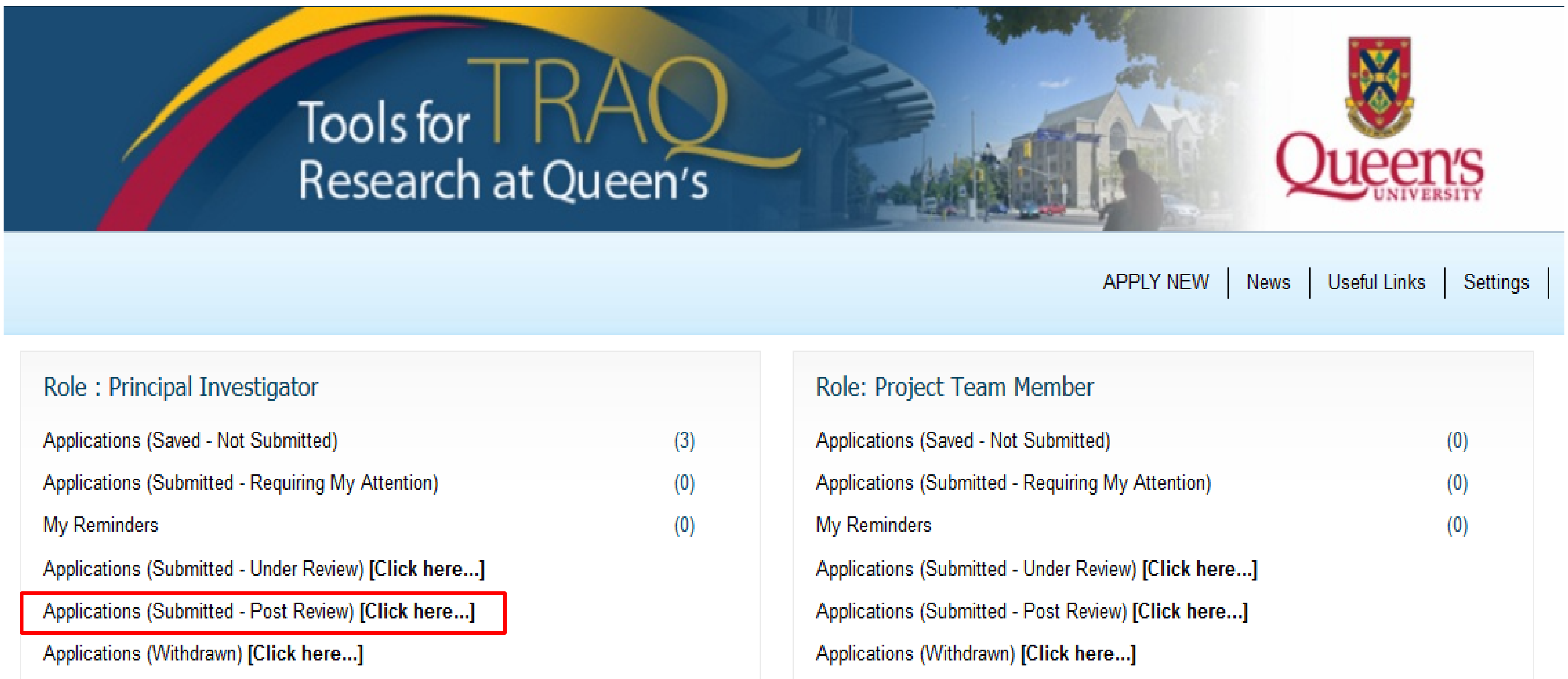
Applications Requiring Revisions

- If the reviewer(s) require any revisions, the application will be pushed back to the applicant(s). At this stage, you will be able to edit the application by clicking on **Applications (Submitted – Requiring my Attention)**. The P.I., Research Coordinator and Supervisor will receive an automatic email notifying them that they have an application which requires their attention. Any member of the team will be able to edit the application, but the P.I. is the only person who has the ability to re-submit the application.



Approved Applications

- Once the application has been approved, the P.I., Research Coordinator and Supervisor will receive a formal approval letter and email. The application can no longer be modified but is available for viewing under **Applications (Submitted – Post Review)**



Need assistance/have a question?

Contact the TRAQ Helpdesk

(613) 533-6000, ext. 78426

Email: traq@queensu.ca