



## Seton Institutional Review Board and Office of Research Administration TOPAZ Submissions Frequently Asked Questions (FAQs)

Please click on any of the following questions to access their corresponding answers:

- **I am trying to access the website for TOPAZ, but my browser keeps getting an error. What do I do?**
- **How do I access TOPAZ using Citrix?**
- **What username and password do I use to log into TOPAZ?**
- **Can I copy and paste in TOPAZ?**
- **What is the Presubmit button? Do I use it to submit to the SIRB/ORR?**
- **Where do I attach the signed and dated CVs and CITI Trainings?**
- **(Section 2) How do I change the Principal Investigator when creating a new submission?**
- **(Section 2) Why is PI information needed if it is already inputted into Staff Information?**
- **(Section 2) Is the Co-Author required?**
- **(Section 2) Does PI need to be listed in Protocol Associates?**
- **(Section 2) What is "Allow Access to Protocol"?**
- **(Section 2) What is "Associate Can View Emails"? Does that mean they can view the emails? Or does that mean they will receive the emails?**
- **(Section 16) Can I add multiple attachments to one question?**
- **(Section 17) How do I complete a conflict disclosure?**
- **(Section 17) Does the PI need to e-sign the PI Assurance Statement? How do they do so?**
- **(Section 17) I accidentally e-signed the PI Assurance Statement and I am not the PI. What do I do?**
- **(Section 18) Do I need to complete anything in the Office Use Only section?**

### **I am trying to access the website for TOPAZ, but my browser keeps getting an error. What do I do?**

This is likely because you are not behind the Seton firewall. Please keep in mind that you will need to be logged into the Seton Intranet in order to access TOPAZ. If you are offsite and have Internet access, you can access TOPAZ via Citrix. Please go to [citrix.seton.org](http://citrix.seton.org) in your web browser, log in using your Seton username and password, and select either Intranet or TOPAZ. Either will work. Selecting TOPAZ will take you directly to the application. Selecting Intranet will take you to the Seton Intranet page. From there, hover your cursor over Web Applications, then select TOPAZ Elements.

[Back to top.](#)

### **How do I access TOPAZ using Citrix?**

If you are offsite and have Internet access, you can access TOPAZ via Citrix. Go to [citrix.seton.org](http://citrix.seton.org) in your web browser, log in using your Seton username and password, and select either Intranet or TOPAZ. Either will work. Selecting TOPAZ will take you directly to the application. Selecting Intranet will take you

to the Seton Intranet page. From there, hover your cursor over Web Applications, then select TOPAZ Elements. If you have never used Citrix before on your computer, you will have to download the Citrix Receiver. You can do this by going to [www.citrix.com](http://www.citrix.com), clicking “Downloads,” choosing “Citrix Receiver,” and following the remainder of the instructions on the website. This is a free download and will allow you to use Citrix on your computer.

Back to top.

### **What username and password do I use to log into TOPAZ?**

TOPAZ is tied in directly with Seton’s Active Directory. You should use your Seton username and password to log into TOPAZ. (If you use a work computer at Seton, this is your Windows username and password that you use to log into your work computer.) Be sure you are in the “TOPAZ IRB and COI” database by choosing that option in the drop-down menu at the login screen. If you are having issues logging in, you may not have been added to the TOPAZ staff/username list yet. Please contact an IRB Coordinator for assistance.

Back to top.

### **Can I copy and paste in TOPAZ?**

Yes. However, you cannot right-click in the application. In order to copy, cut, and paste, you will need to use the keyboard shortcuts. For copy: Ctrl+C, for cut: Ctrl+X, For paste: Ctrl+V. On a MAC, you will use the Command key instead of the Ctrl key.

Back to top.

### **What is the Presubmit button? Do I use it to submit to the SIRB or ORA?**

The Presubmit function is entirely optional. This allows for you to – prior to formal submission to the SIRB and ORA – “presubmit” your submission to a staff member of your choice. That staff member will then have read-only access to your submission. After reviewing the submission, that staff member can sign off on the submission using the “Signoff” button. Their e-signature is recorded in the system. You should NOT use this button to submit your study officially to the ORA and SIRB. You should use the “Submit” button to actually submit the study. Please note that even though you have “presubmitted” your study to another staff member, you can still formally submit to the ORA/SIRB at any time (e.g. if that staff member is taking too long to sign off on it).

Back to top.

### **Where do I attach the signed and dated CVs and CITI Trainings?**

The signed and dated CVs and CITI Trainings should not be attached anywhere in TOPAZ. By clicking on the blue (i) icon next to a person's name, you will be able to check whether a person's CV or CITI is current. If they are not current in our files, you will need to email the CVs and/or CITI Trainings to an IRB Coordinator. The IRB Coordinator will then update that information into TOPAZ. Please remember that

signed and dated CVs are required for all investigators. CITI Training is required for all study personnel, regardless of role. Research Coordinators are required to complete the Good Clinical Practice course in addition to the Basic Course for Human Subjects Curriculum.

[Back to top.](#)

#### **How do I change the Principal Investigator when creating a new submission?**

In the Principal Investigator question, click on the human silhouette with a green and white (+) icon in the bottom left hand corner of the question box. A staff list will pop up asking you Select Staff. From here, you can select the appropriate PI by clicking on their name. Only certain staff members are designated as PIs and will populate in this list. If you do not see a PI on this list, please contact an IRB Coordinator to have them either added to the system or have them designated as a PI.

[Back to top.](#)

#### **Why is PI information needed if it is already inputted into Staff Information?**

Sometimes the contact information we have on file for a PI is not current or is not the preferred contact information for IRB correspondence, so we ask that this information be inputted for each study protocol in order to be sure this is correct.

[Back to top.](#)

#### **Is the Co-Author required?**

No. The Co-Author is an optional field. Any question designated with a **red asterisk** is a required question.

[Back to top.](#)

#### **Does the PI need to be listed in the Protocol Associates question?**

No. However, the Author and Co-Author do.

[Back to top.](#)

#### **What is "Allow Access to Protocol"?**

By checking "Allow Access to Protocol" for a protocol associate, this person has full rights to this study in TOPAZ. This means they can access the study and make changes, submit, create amendments, renewals, interim reviews for the study, and view all system-generated emails related to the study. They are considered a "Co-Investigator" within TOPAZ.

[Back to top.](#)

**What is “Associate Can View Emails”? Does that mean they can view the emails? Or does that mean they will receive the emails?**

By checking “Associate Can View Emails” for a protocol associate, this person has rights to view all system-generated emails related to the study. They can view these emails by clicking on the blue (i) icon for Protocol Information and selecting the “Emails” tab. They will not necessarily receive the emails. The PI and Authors will receive the emails.

Back to top.

**Can I add multiple attachments to one question?**

Yes. After clicking on the paperclip icon in a question box, a screen will pop up called “Add Links and Attachments.” By clicking on the paperclip icon with the green (+) at the middle top of this pop up screen, you can add a designated spot for one attachment. From there, you can “Browse To File...” to search for the attachment on your computer. If you wish to add another attachment, you can click on the paperclip icon with the green (+) again and a second designated spot for another attachment will appear. And so on and so forth...

Back to top.

**How do I complete a conflict disclosure?**

As of October 22, 2012, the Conflicts Disclosure module is not available to researchers. Eventually all study personnel will be required to complete one via the Conflicts Disclosure module in TOPAZ. For now, the ORA will accept a “Yes” answer to this question until the Conflicts Disclosure module is made available. At that time, this will be a viability check for any studies submitted to the ORA.

Back to top.

**Does the PI need to e-sign the PI Assurance Statement? How do they do so?**

Yes. If anyone other than the PI e-signs this question, the submission will be returned to you as Not Viable. The PI will need to be logged into TOPAZ, navigate to the PI Assurance Statement question, read through all responsibilities required as the PI, click on “Agree”, and “Save” (floppy disk icon in the top menu bar). Once the PI clicks “Save”, a screen will pop up asking for the PI’s username and password. After entering their username and password, their e-signature has been logged by the system. Please note the system will only take the username and password for whoever is logged in at that moment.

Back to top.

**I accidentally e-signed the PI Assurance Statement and I am not the PI. What do I do?**

If this happens, please click on “Agree” again to remove your answer from this question and click “Save”. At that point, the PI should be able to log in and e-sign the question.

Back to top.

**Do I need to complete anything in the Office Use Only section?**

No. This is used only by IRB Administrators. You are not able to populate any of the questions in this section. However, you should be able to find your most current IRB approval letter and stamped consent forms (if applicable) in the first question of this section.

[Back to top.](#)