TOPAZ: User Guide for PI Certifications

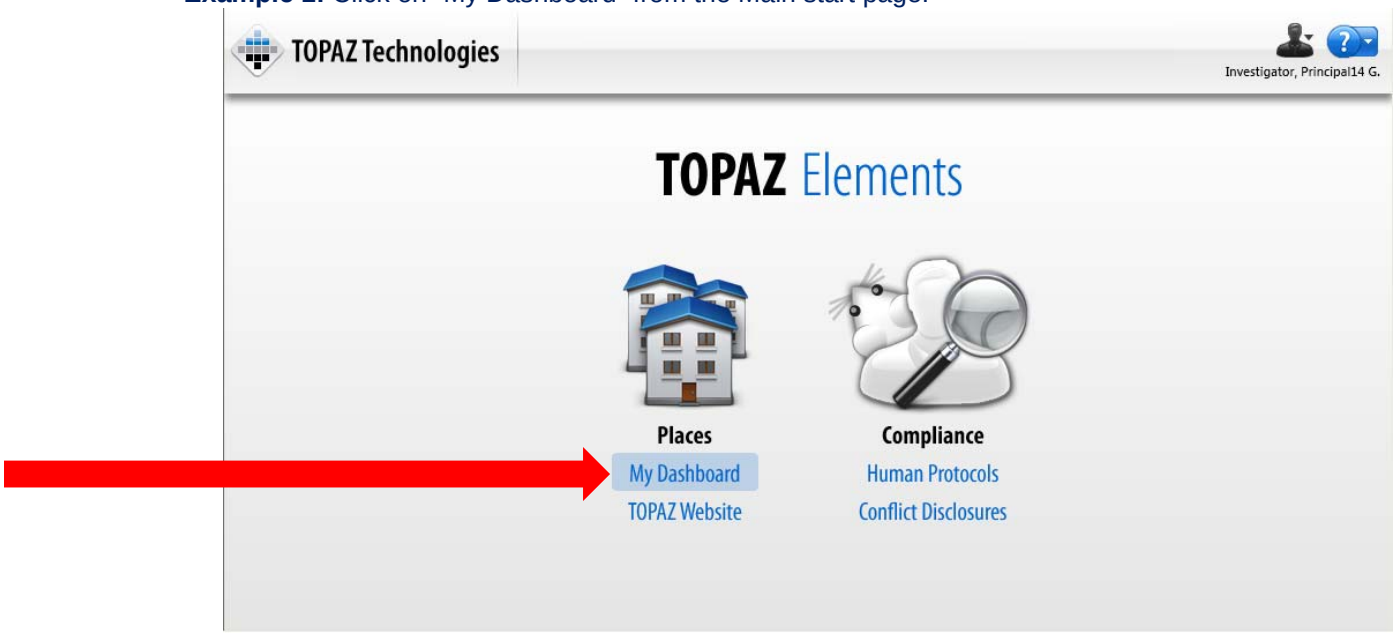
General Instructions:

- Use this guide to assist with e-signing the PI Certification questions within the TOPAZ application.
- The study and PI used here are strictly for example purposes only.

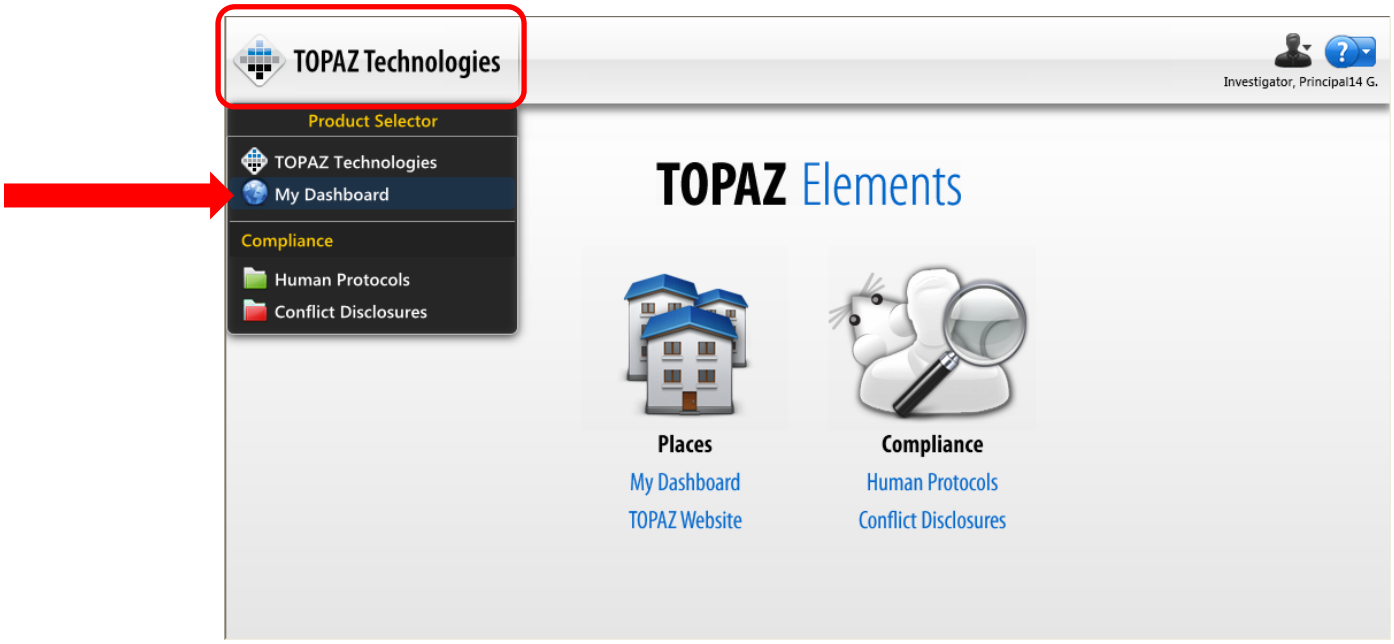
PART 1: ACCESSING THE STUDY

1. First, you should access the study that you want to e-sign the PI Certification/PI Assurance Statement for. You can do this by navigating to your Dashboard. There are a couple ways to access your Dashboard. See screenshots below.

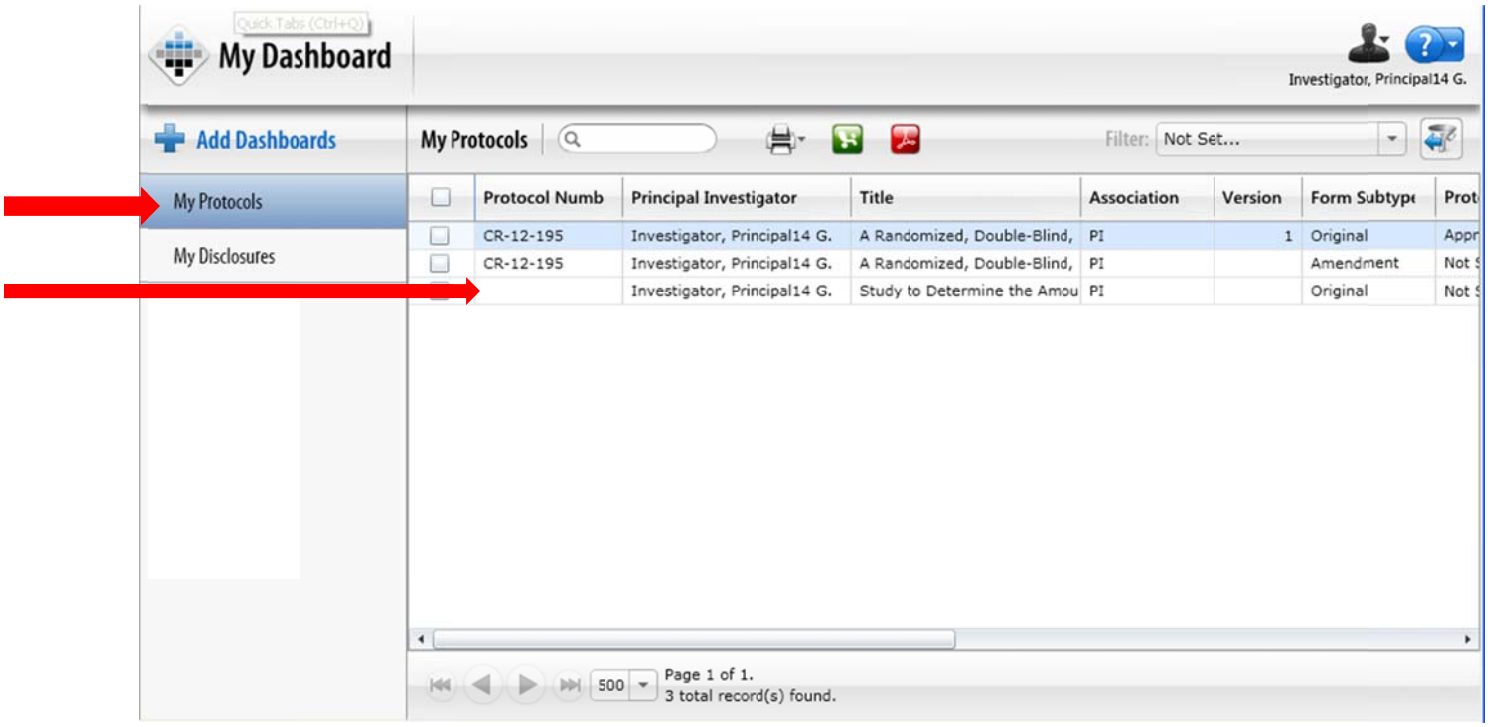
Example 1: Click on "My Dashboard" from the Main start page.



Example 2: Click on "My Dashboard" from the Product Selector menu, which you can access by clicking on the top-left button.



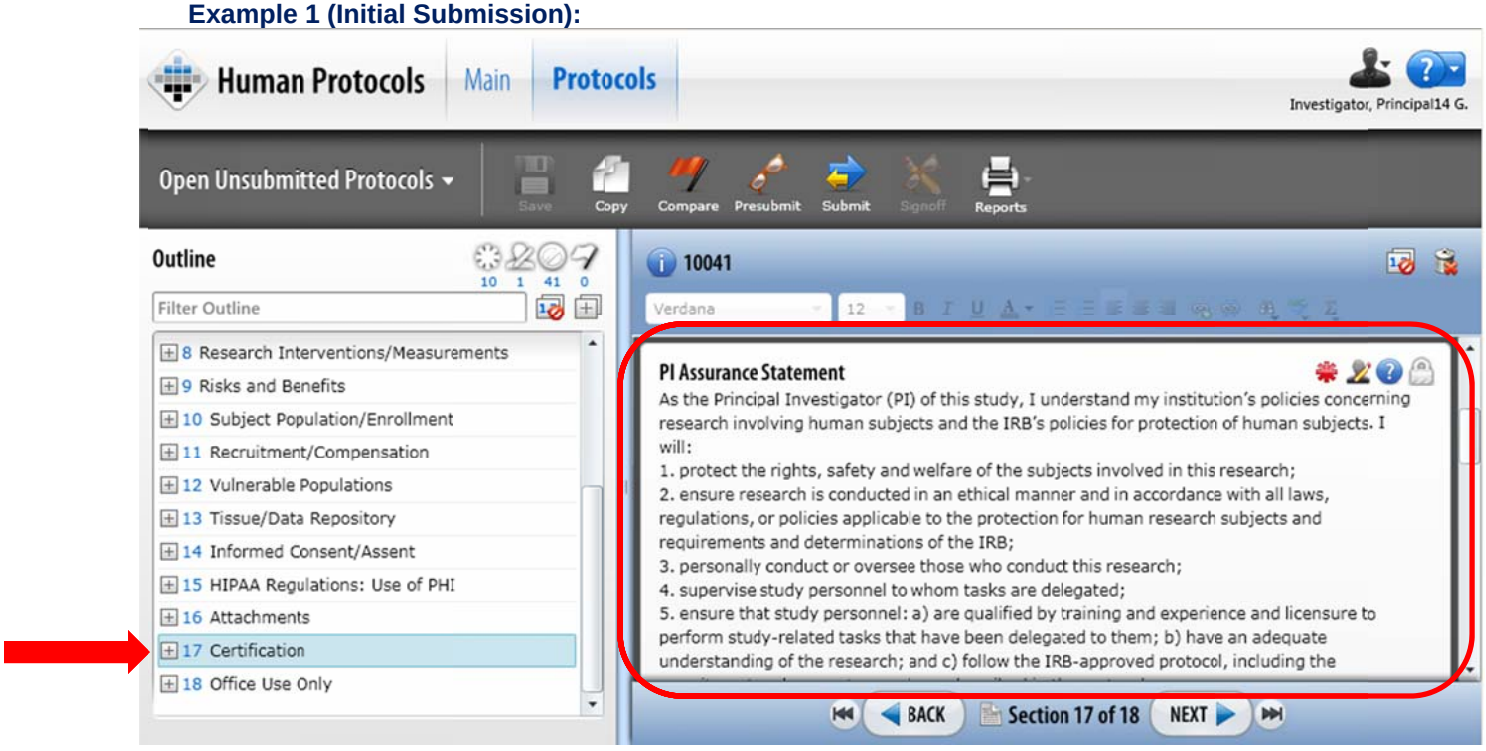
2. Once you are in your Dashboard, be sure you are in the “My Protocols” Dashboard in order to access your IRB studies and then select the study submission form that you are signing off on. You can do this by clicking anywhere on the line of that study. See screenshot below.



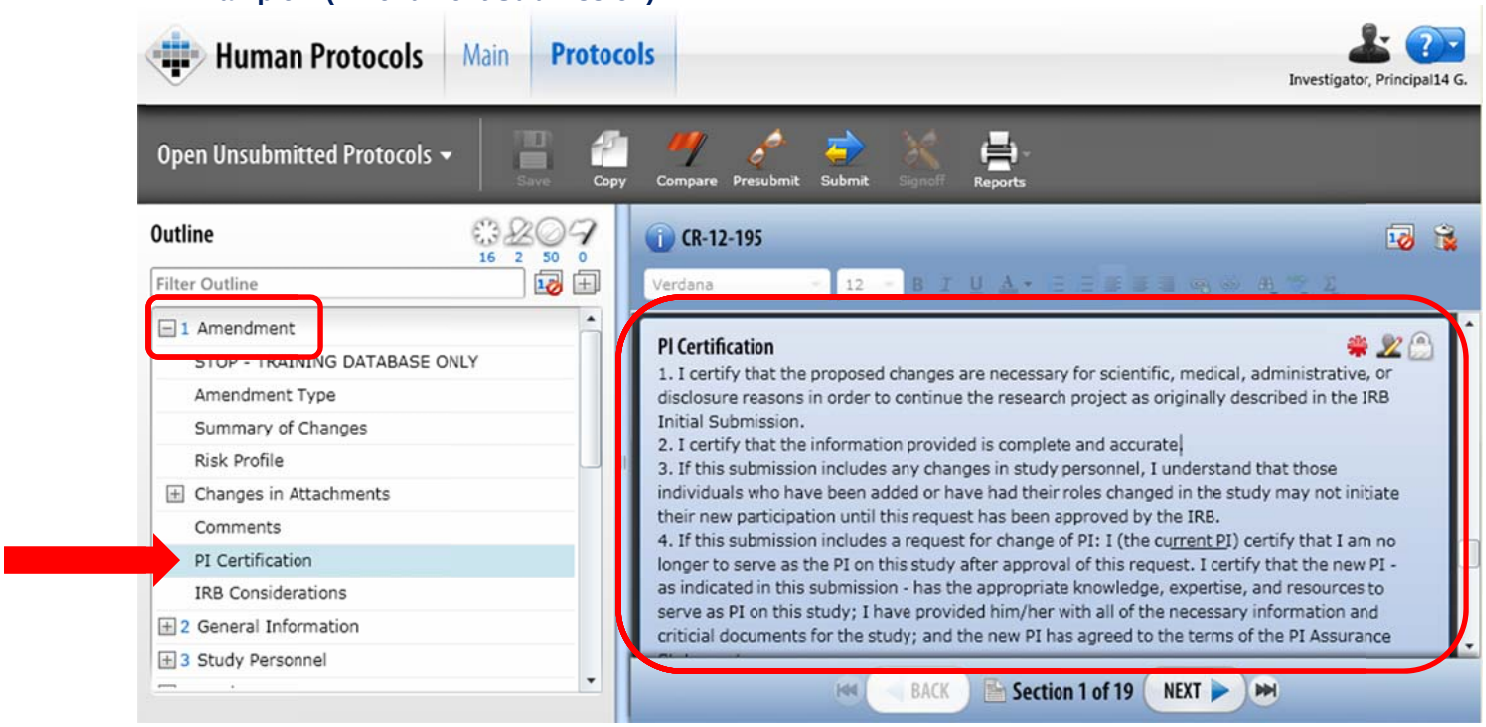
PART 2: E-SIGNING THE QUESTION

1. You should now navigate to the question requiring the e-signature. If this is an Initial Submission, the question will be in Section 17: Certification. If this is a subsequent submission (renewal, amendment, miscellaneous request, etc.), the question will be in the top section. See screenshots below for examples of each.

Example 1 (Initial Submission):



Example 2 (Amendment Submission):

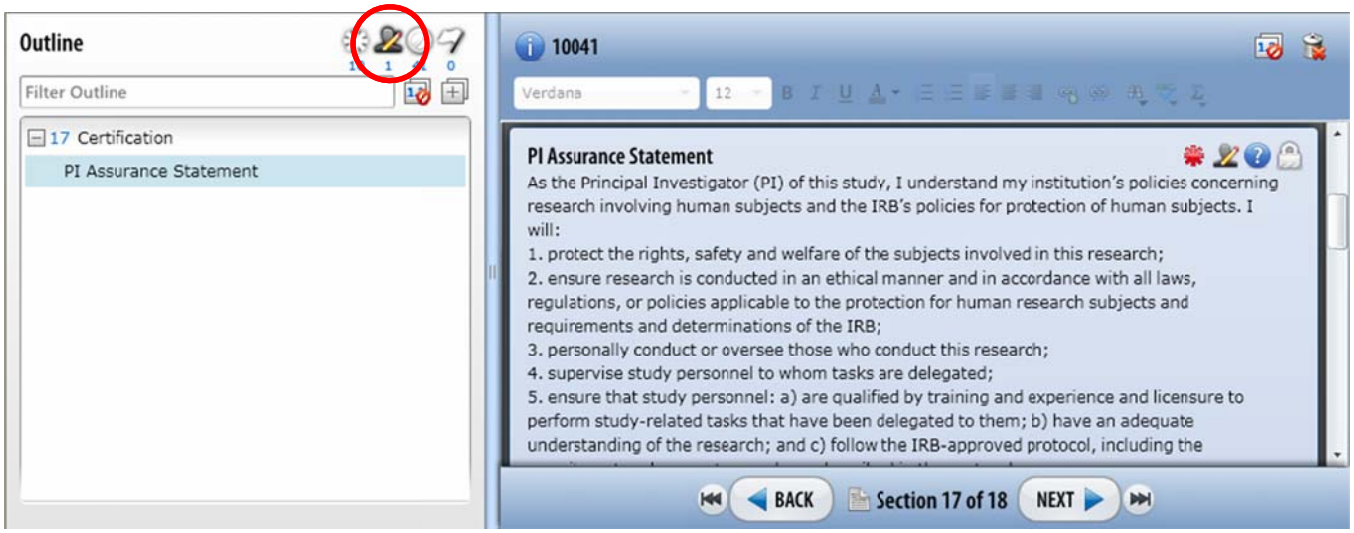


There are a couple of ways to get to the e-signature questions.

Example 1: You can click directly in the Outline on that question or section.

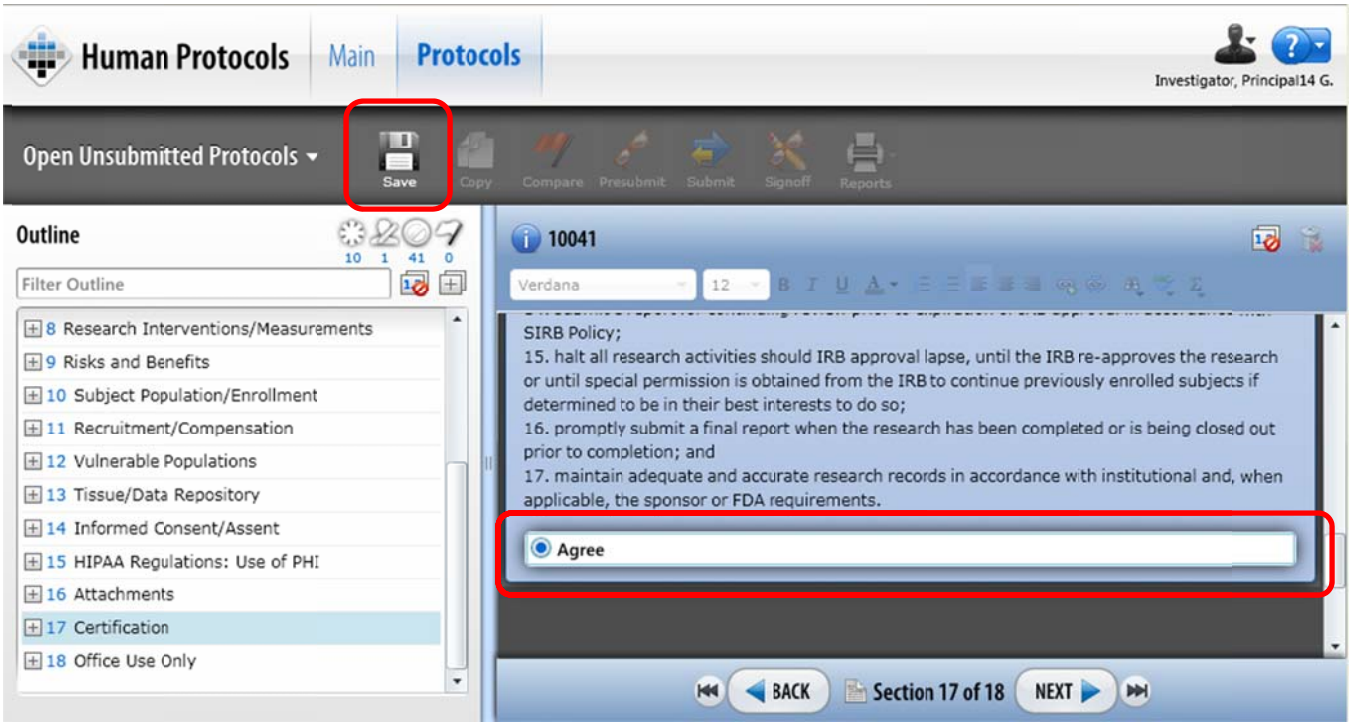
Example 2: You can use the scroll bar on the right of the screen and/or click on the "Next" button at the bottom of the screen until you reach the question.

Example 3: You can filter your Outline for all questions requiring an e-signature. Do this by clicking on the e-signature icon at the top of your Outline. This will bring up in your Outline <u>only</u> the questions where an e-signature is required. See screenshot below.

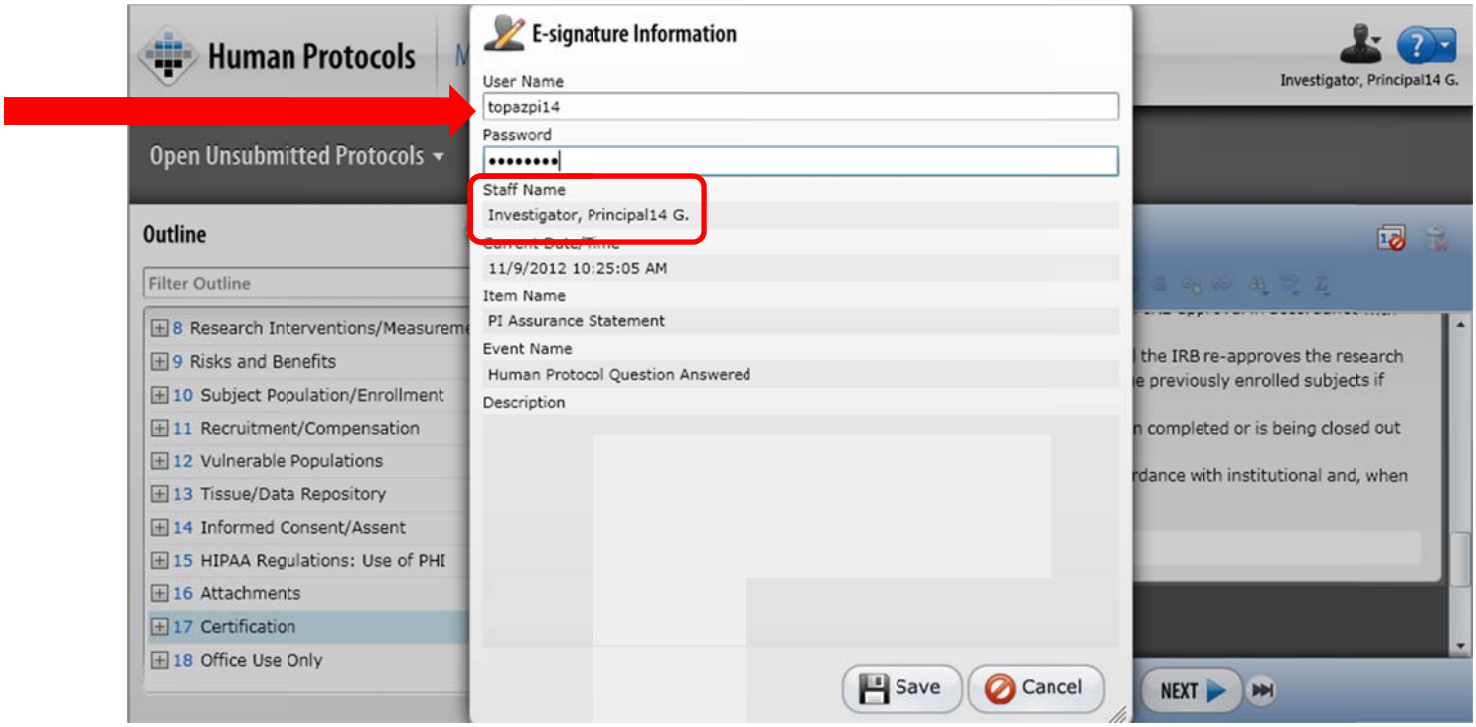


Please note that only one e-signature is required per submission. **If you are e-signing a subsequent submission (renewal, amendment, miscellaneous request, etc.), you will only need to e-sign the PI Certification question in the top section of the renewal, amendment, miscellaneous request, etc. form.**

2. Once you are at the PI Assurance/Certification question, read through each of the points. Click on “Agree” and then “Save” at the top (floppy disk icon). See screenshot below.



3. An “E-signature Information” screen will pop up asking for the logged in user’s username and password. Enter your Seton username and password and click “Save”. See screenshot below.

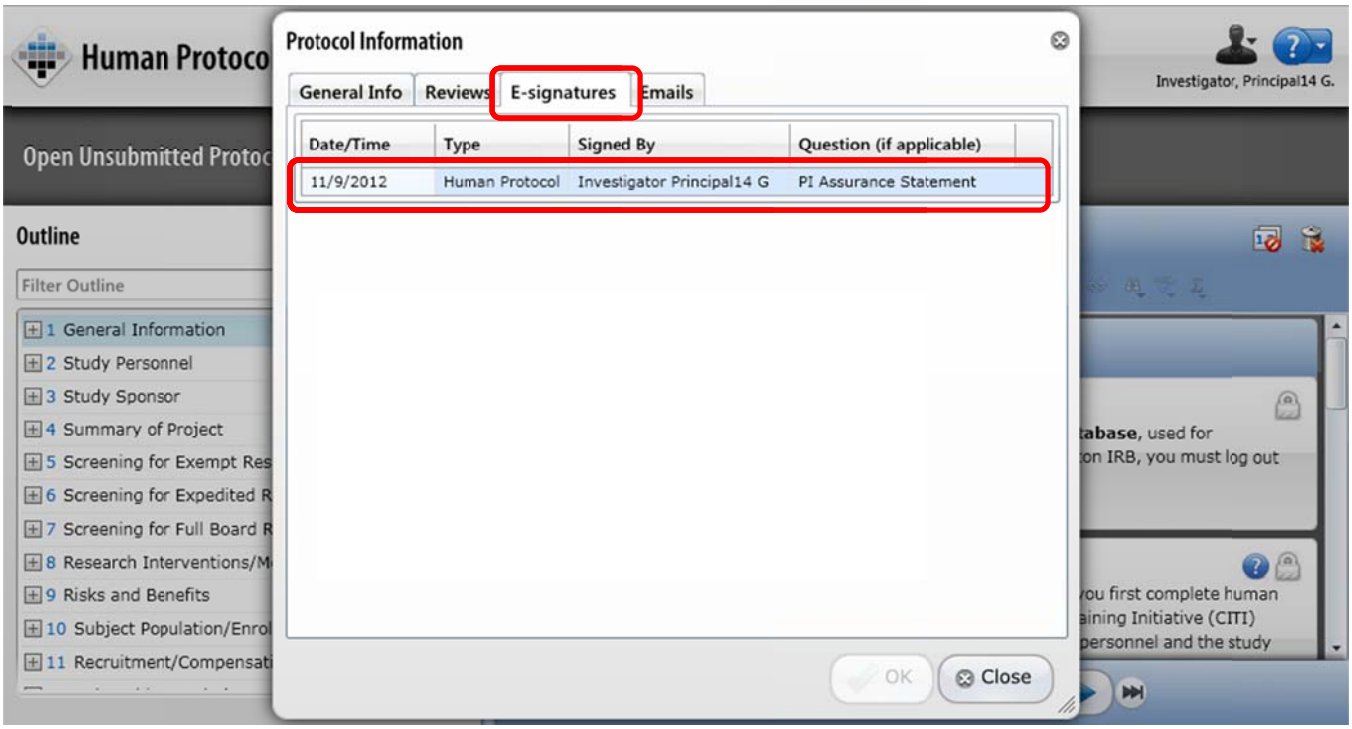


Your e-signature is now recorded in the system. Please note that it will **only** accept the currently logged in user’s username and password, so the PI **must** be logged in in order to e-sign this question.

PART 3: VERIFYING THE E-SIGNATURE

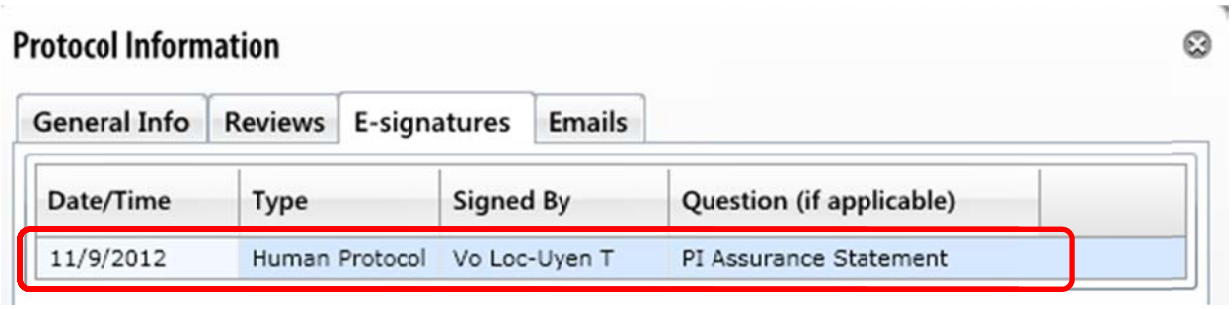
1. To verify who has e-signed the PI Assurance/Certification question, click on the blue (i) icon to access Protocol Information.

2. The Protocol Information screen will pop up. From there navigate over to the "E-signatures" tab and verify who signed the PI Assurance Statement or PI Certification question. See screenshot below.

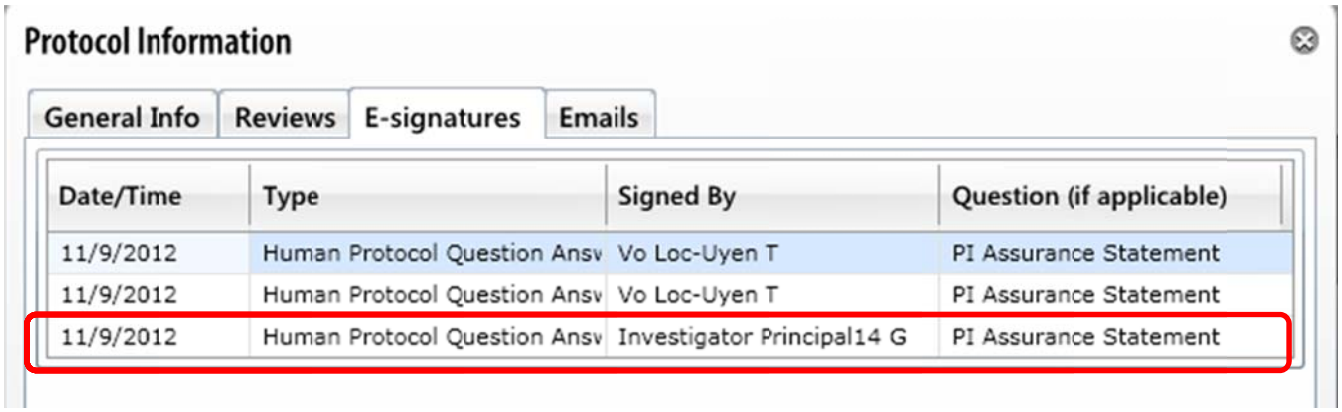


PART 4: RE-SIGNING THE QUESTION (IF NEEDED)

If someone other than the PI has e-signed the PI Assurance Statement/PI Certification question, the submission will be deemed "Not Viable" and will be returned to you. For example, in the below screenshot you can see that Loc-Uyen e-signed the PI Assurance Statement for this study by mistake. She is not the PI of the study, so the submission will be returned.



If this has occurred, please follow these steps to be sure the PI signs the question:

1. One of the "core team" members will have to uncheck "Agree" in the PI Assurance Statement/PI Certification question and save. That person will then be prompted to enter their username and password since they are making a change to this question. The "core team" members include the PI, Creator, Author, Co-Author, and Key Associates (those associates that have "Allow Access to Protocol" checked).

2. The PI can now log into the system, navigate to the question and e-sign it using the steps provided in this document. The "E-signatures" tab in "Protocol Information" will look similar to the screenshot below where the PI of the study is the last person to e-sign the PI Assurance Statement.