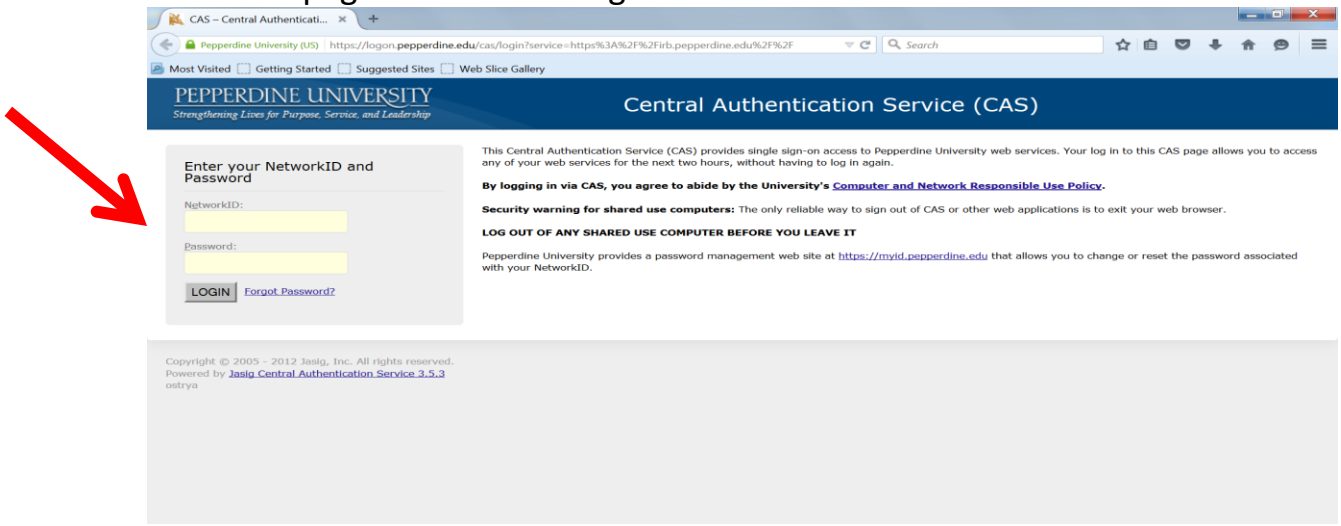
Pepperdine University ePROTOCOL - IRB Student Investigator User Guide

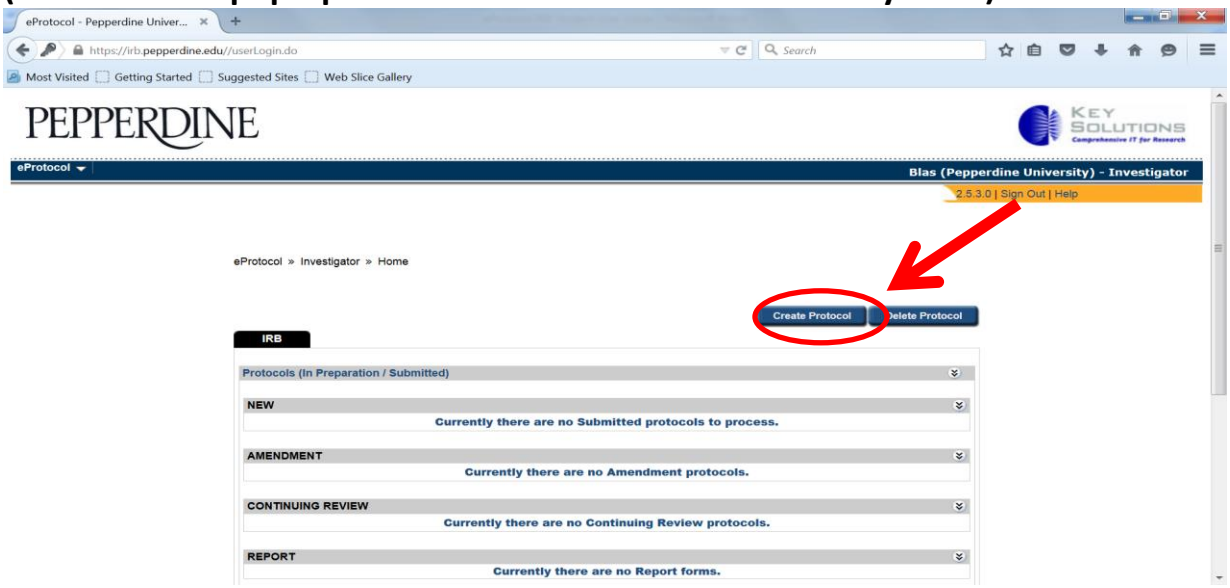
Welcome to eProtocol the online IRB system for Pepperdine University.

To begin creating an online IRB application, please login to the eProtocol IRB system at **https://irb.pepperdine.edu/**.

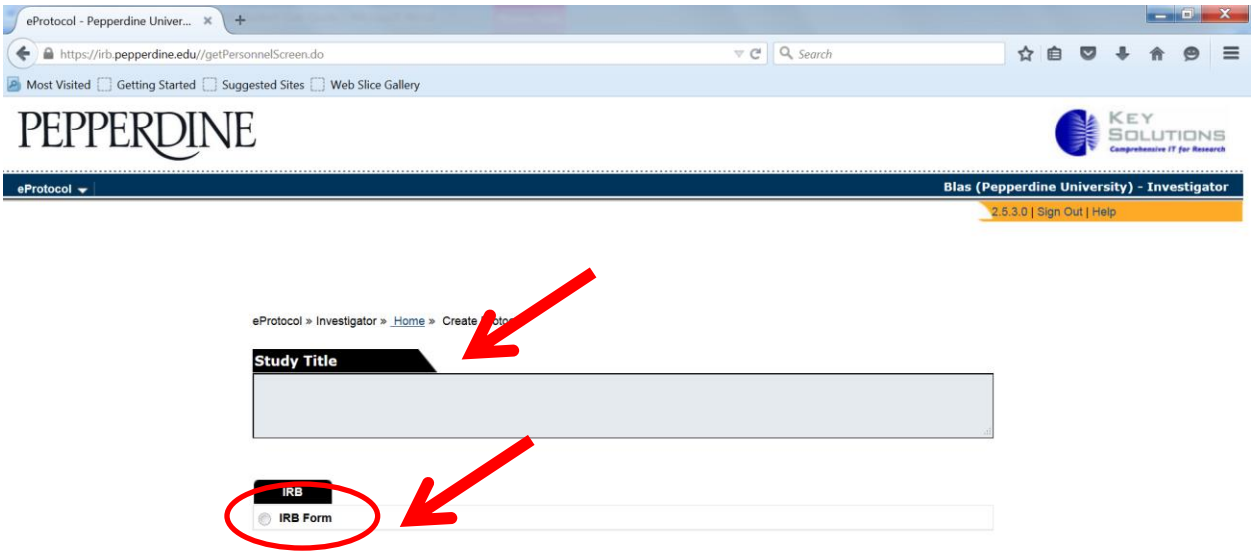
All Pepperdine student users will use their Pepperdine network ID and password through the Central Authentication Service (CAS) system. Recommended browsers include: **Internet Explorer, Safari, and Firefox**. For a glossary of terms, reference page 22 of this user guide.



After login, the IRB system will direct you to the **Investigator Home Page** to create the IRB application. Click the **Create Protocol** button on the top, right of the page. **(*Be sure that pop-up blockers are disabled for this IRB system.)**

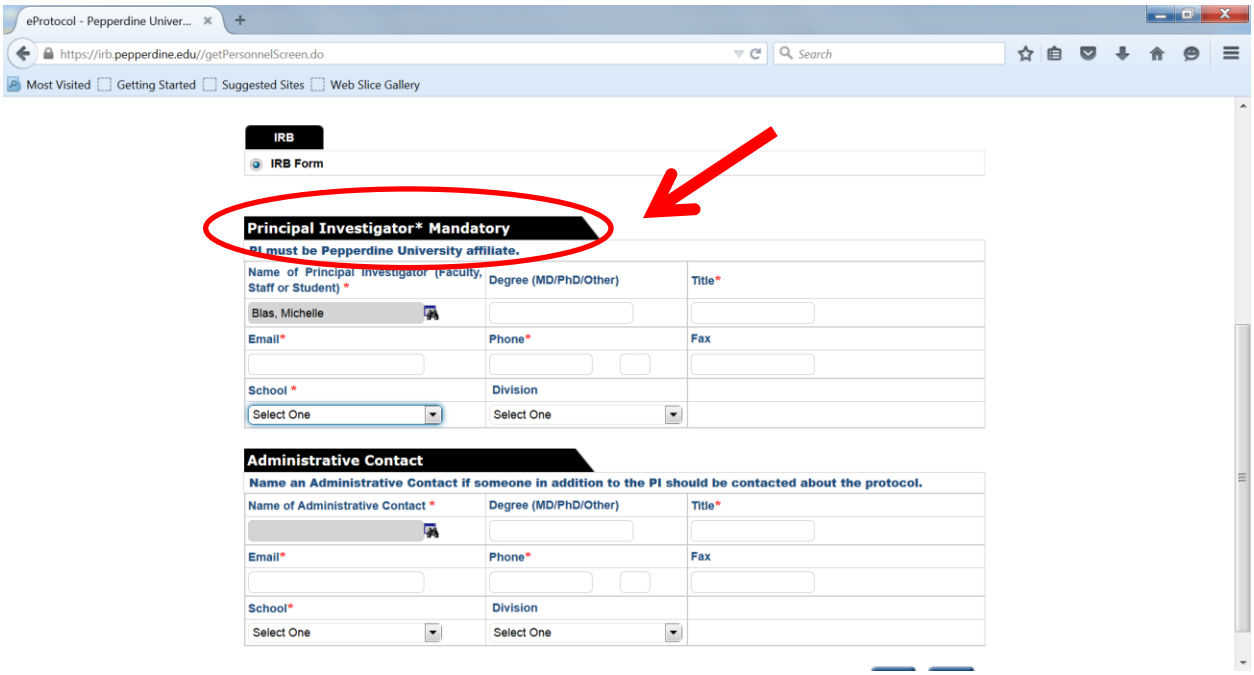


On the next screen, enter the **"Study Title"** and click the **IRB Form** button.

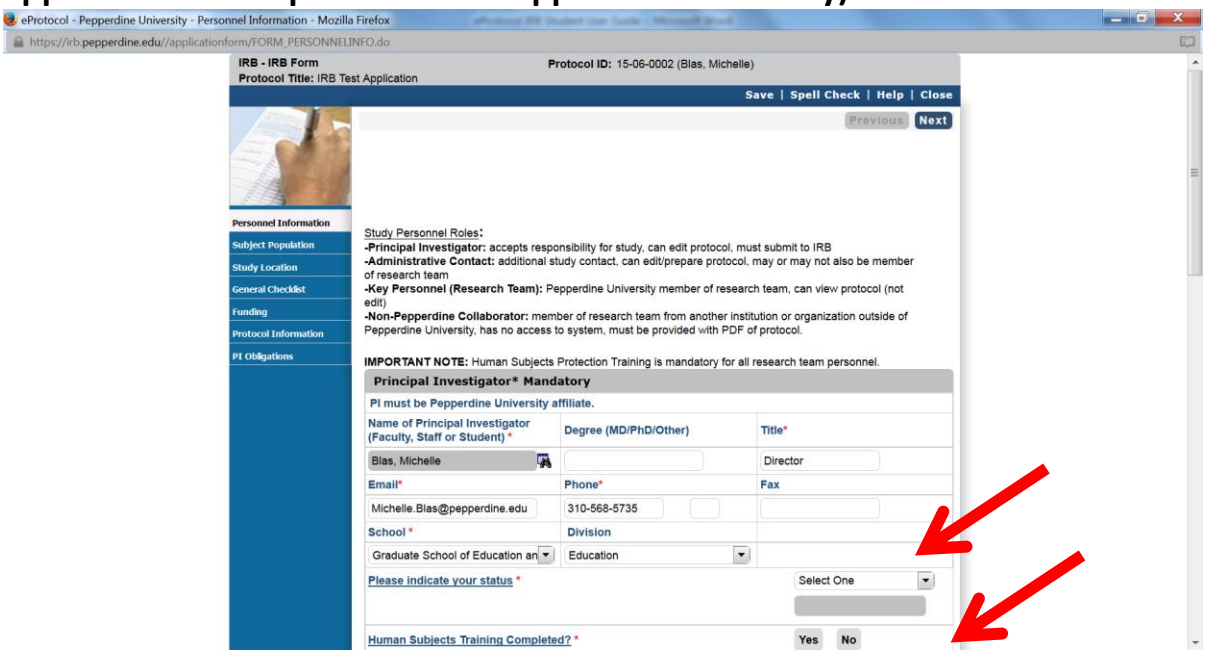


Complete all the **Principal Investigator** information as noted below (required information is astericked in red) and select the **Create** button.

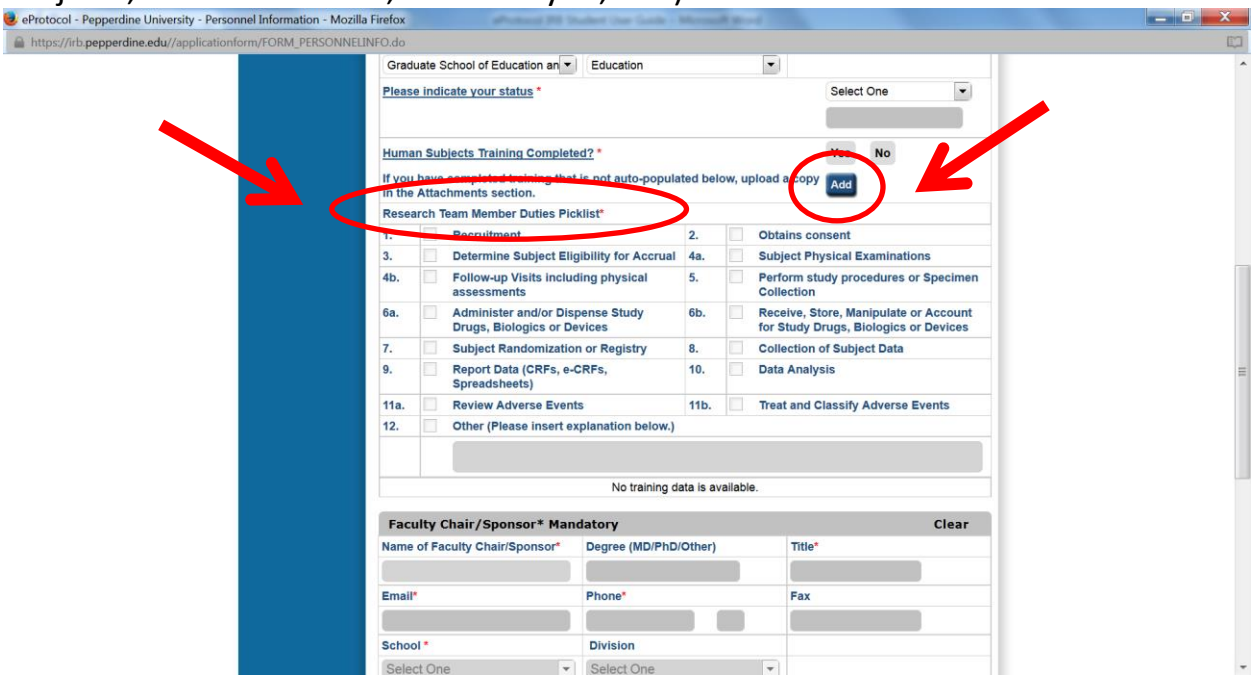
An Administrative Contact can be added to the IRB application, please complete the Administrative Contact information if needed. The Administrative Contact would be in addition to the **Faculty Chair/Sponsor** as required for student users.



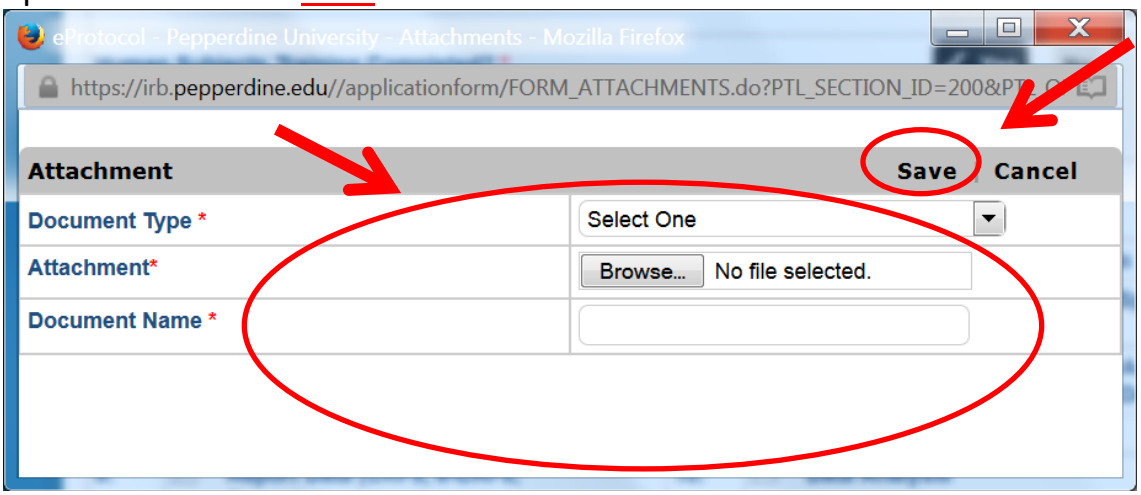
The **Principal Investigator** information that was entered in the previous page will carry over to the IRB application. Select your status as a **Student** and click **Yes** for completing human subjects training. **(This is a requirement for all IRB applications to be processed at Pepperdine University).**



On this same page, upload your **Human Subjects Training Certificate**. Select the **Research Team Member Duties Picklist** as noted below (example, recruiting subjects, obtains consent, data analysis, etc.)

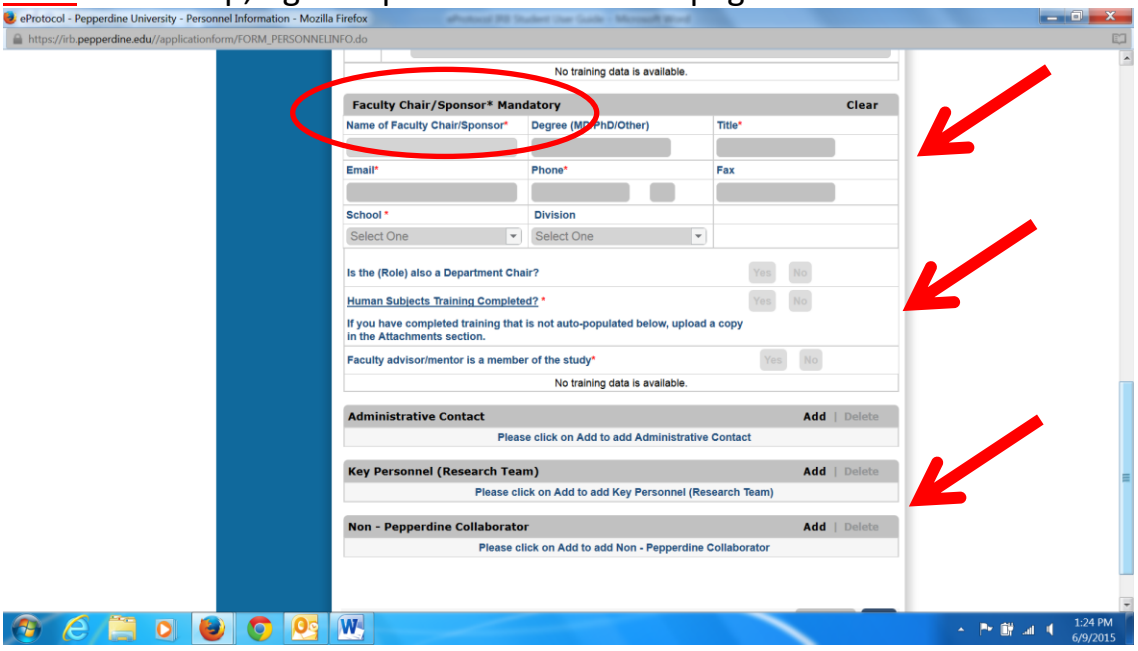


After adding the **Human Subjects Training Certificate**, select the type of document, upload the document, and name the file. Be sure to clearly name the file so that the IRB staff can easily identify the type of document that you have uploaded. Click the **Save** button.

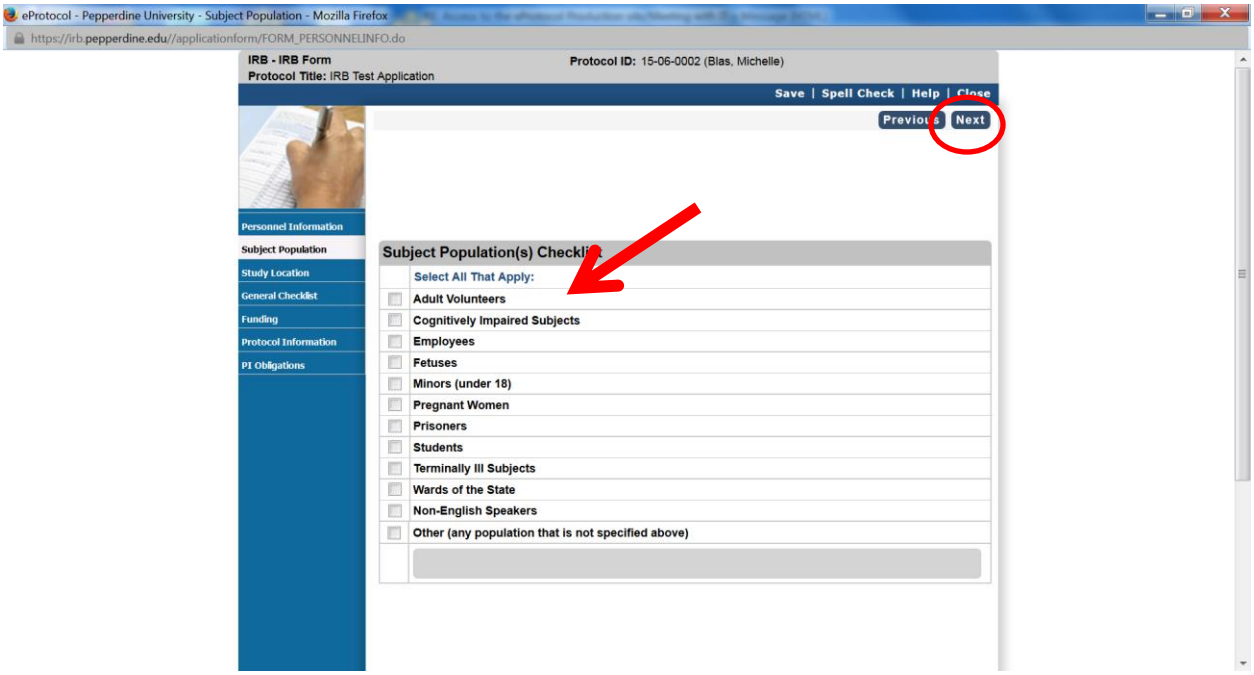


On this same page, select your **Faculty Chair/Sponsor** and enter all the required information. Upload a copy of your **Faculty Chair/Sponsor's Human Subjects Training Certificate** and answer the questions related to your Faculty Chair/Sponsor in this section.

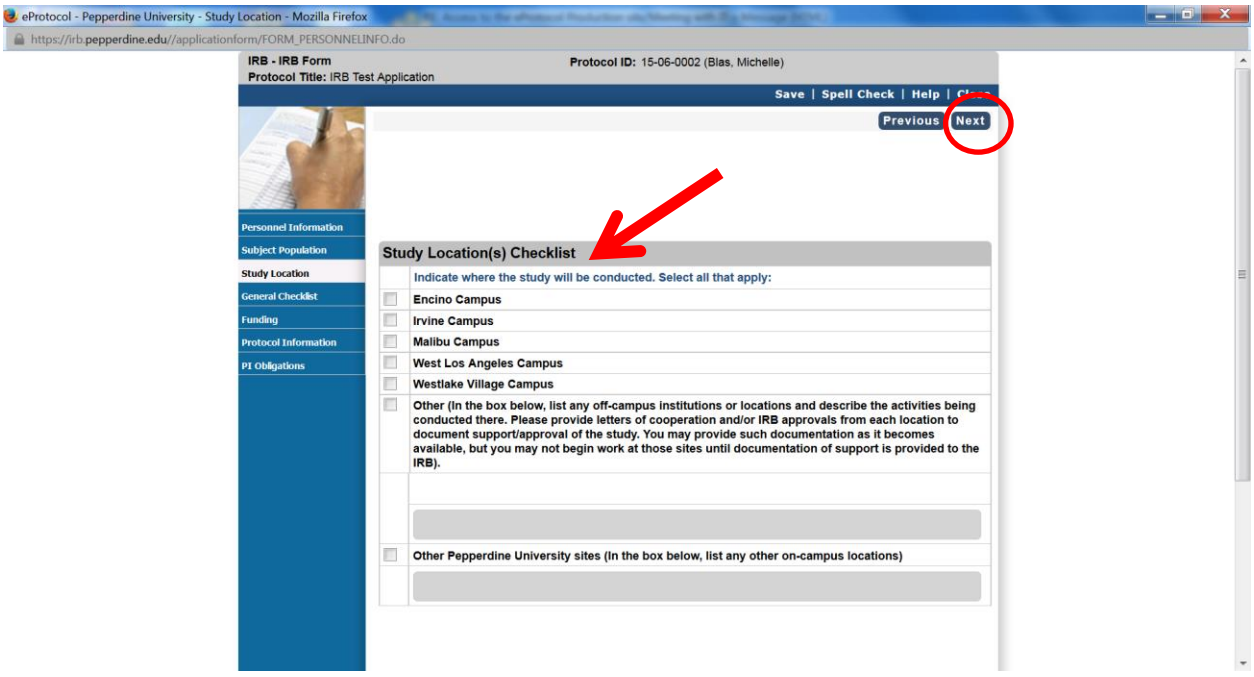
If there are additional research members, add their contact information as an Administrative Contact, Research Team, or Non-Pepperdine Collaborator. Click **Next** on the top, right to proceed to the next page.



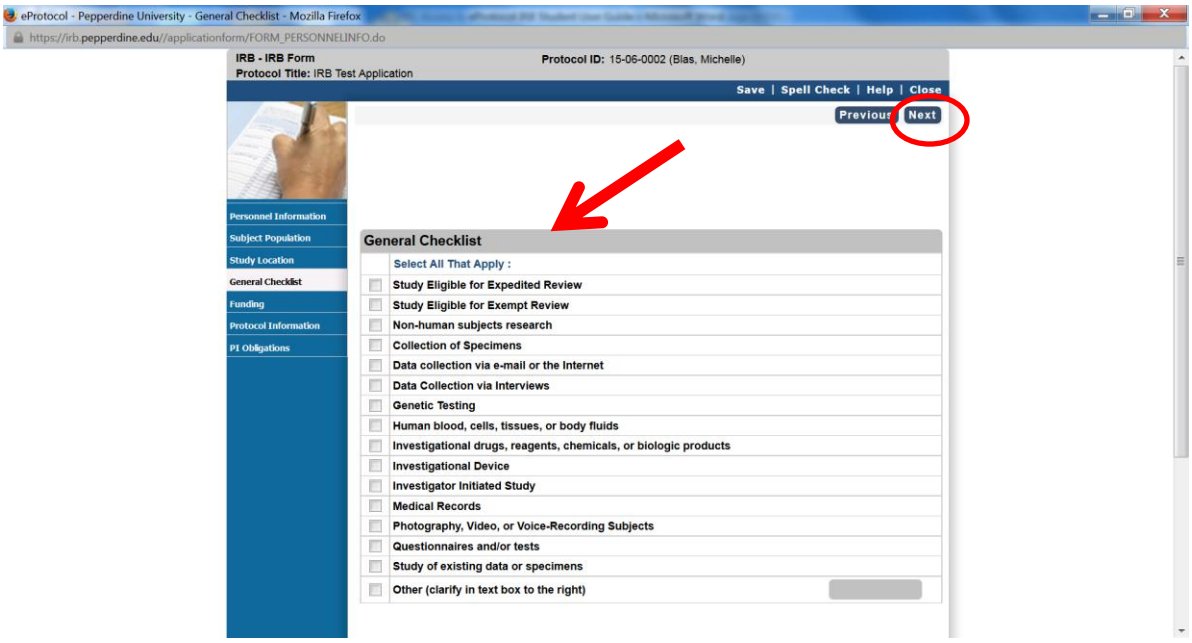
Select the **Subject Population** that will be surveyed as part of the research project. Select all that apply and click the **Next** button on the top, right to proceed to the next page.



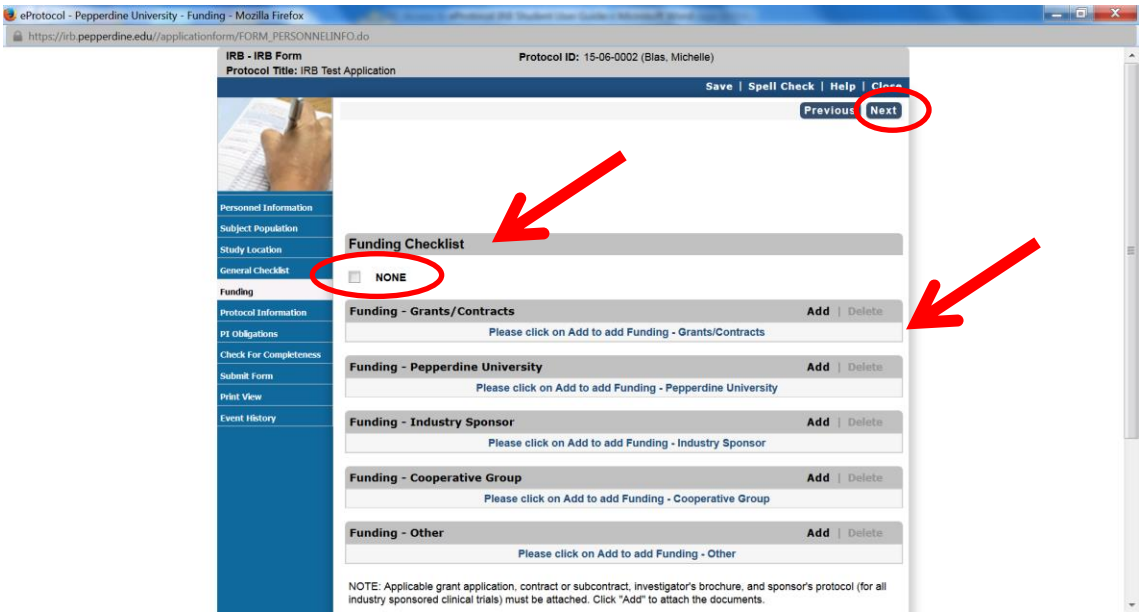
Select the **Study Location(s)** that apply. Indicate the Pepperdine location(s) or select other and type out the location name and attach a site location approval letter. Click **Next** on the top, right to proceed to the next page.



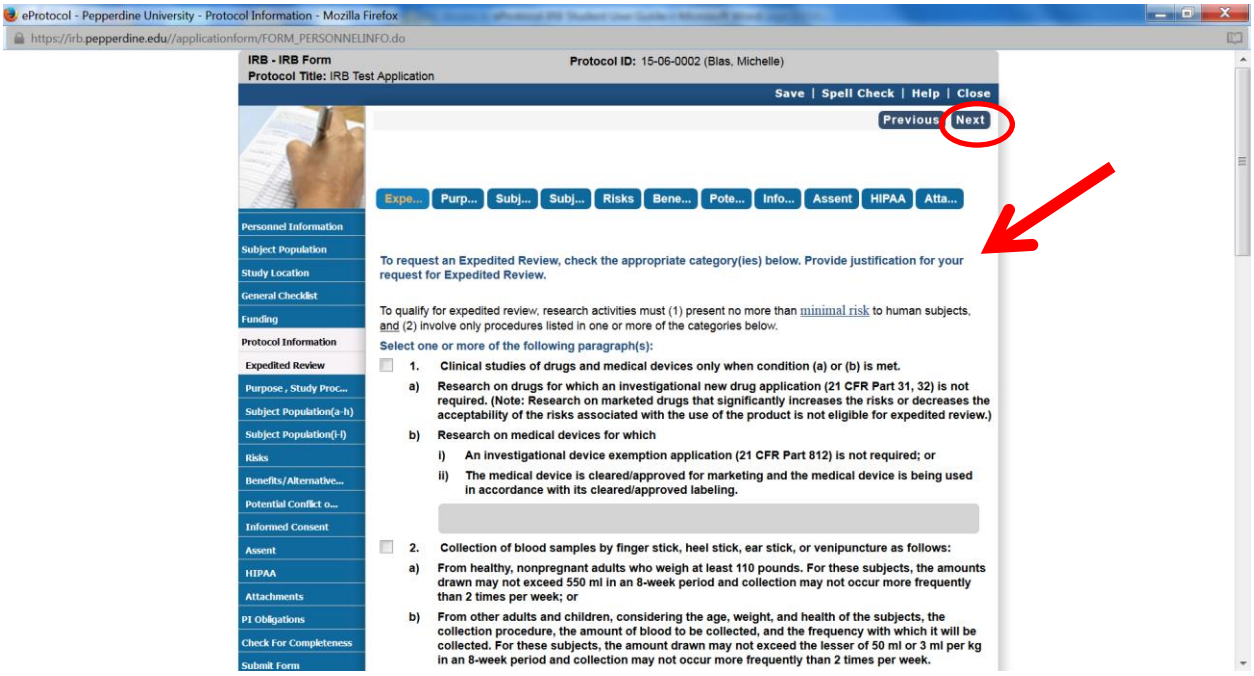
Select the type of study (exempt, expedited, non-human subjects, etc.). Select all that apply. Click **Next** on the top, right to proceed to the next page. Depending on if the study is exempt or expedited will determine the type of questions being asked in the proceeding sections of the IRB application.



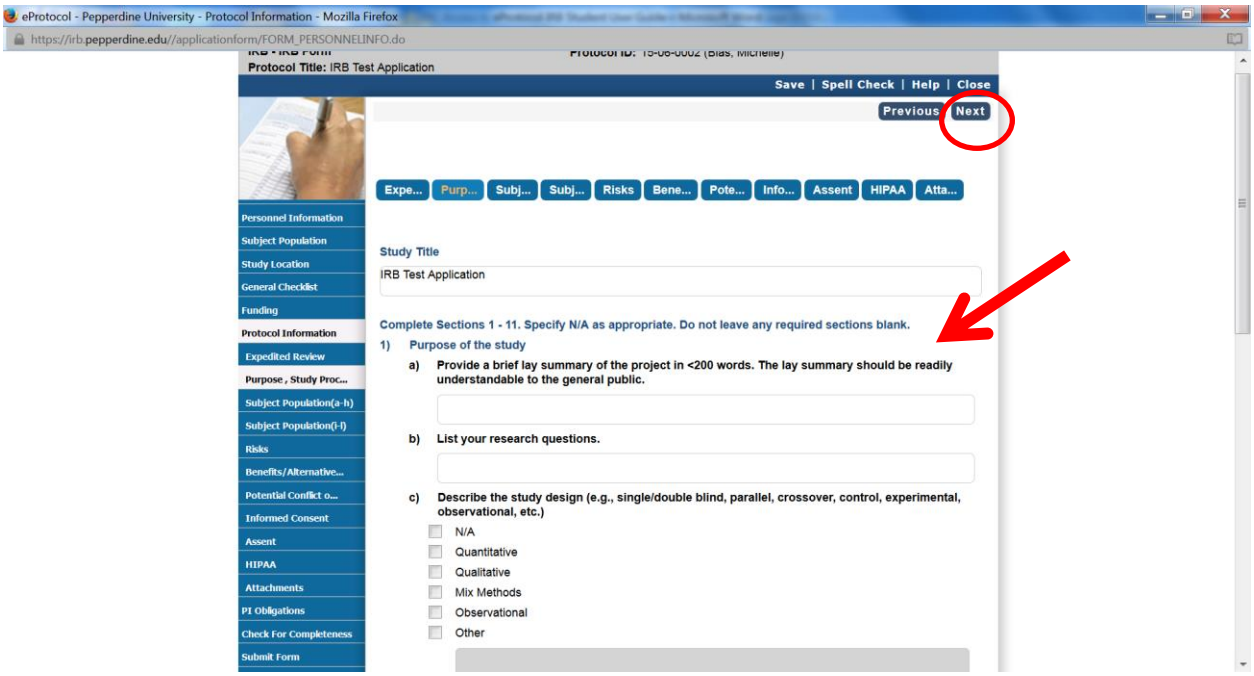
The next section inquires about funding. If the study is not funded by Pepperdine or an outside agency/organization, click **NONE**. If the research is being funded, select the category and provide the name and grant contract for review by the IRB Office. Click **Next** on the top, right to proceed to the next page.



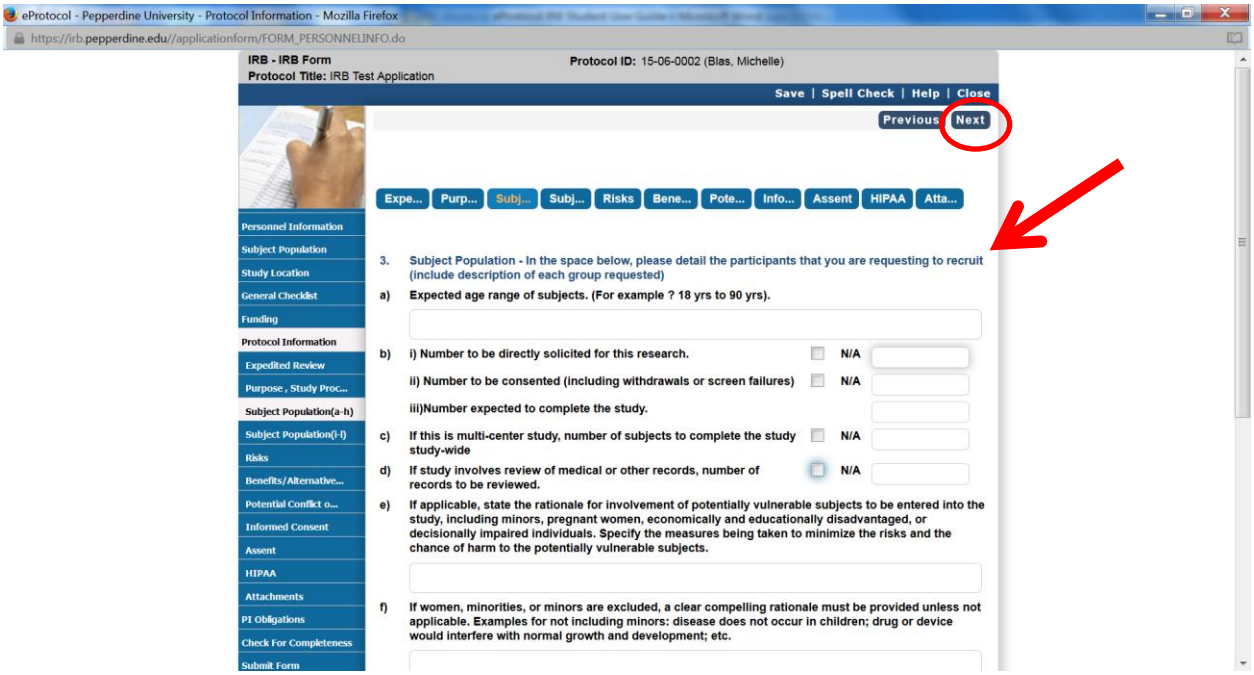
The next section starts the IRB application (**exempt or expedited**). Select the appropriate category depending on if the study is exempt or expedited. Click **Next** on the top, right to proceed to the next page.



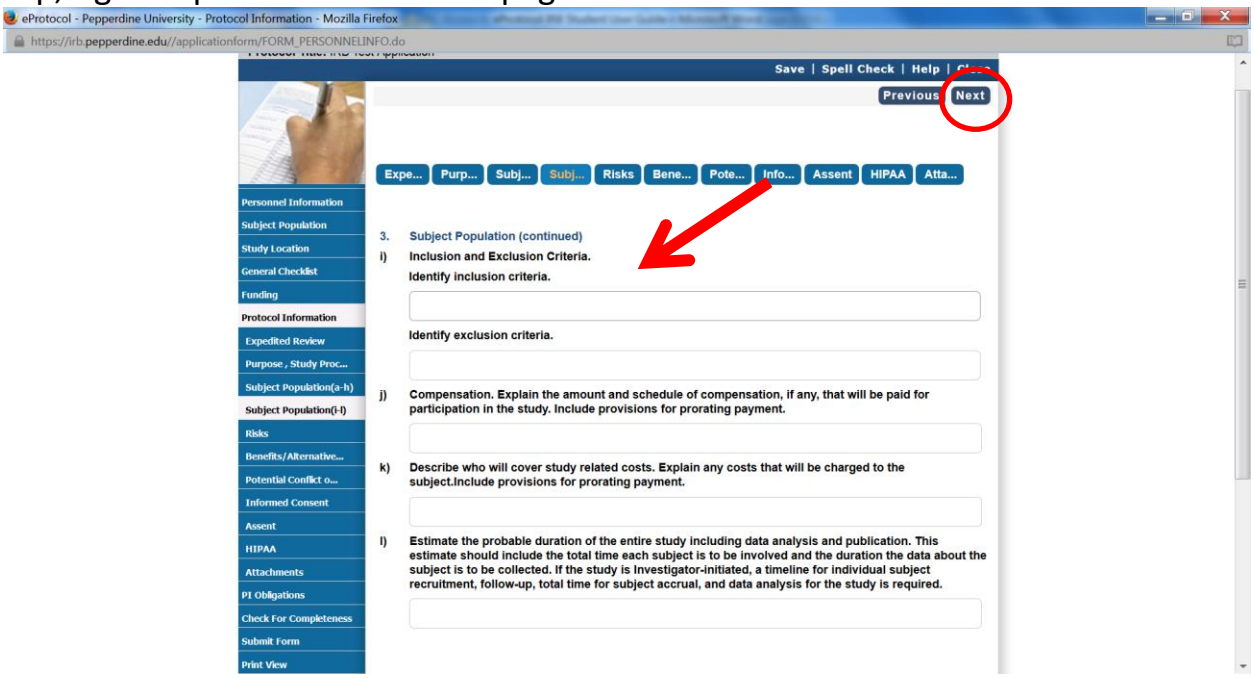
Answer all the questions in the **Purpose Section**. Click **Next** on the top, right to proceed to the next page.



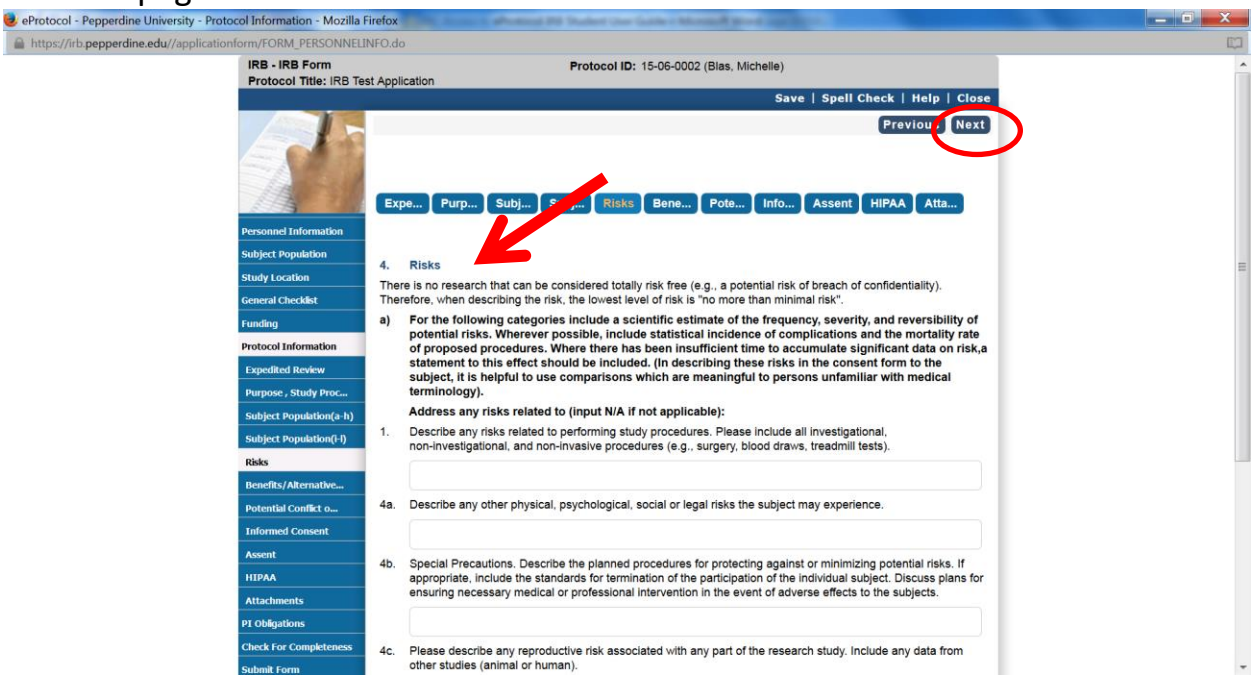
Answer all the questions about the **Subject Population**. Give details of the subjects' ages, number to directly solicit, consented subjects, etc. If non-applicable, select N/A. Click **Next** on the top, right to proceed to the next page.



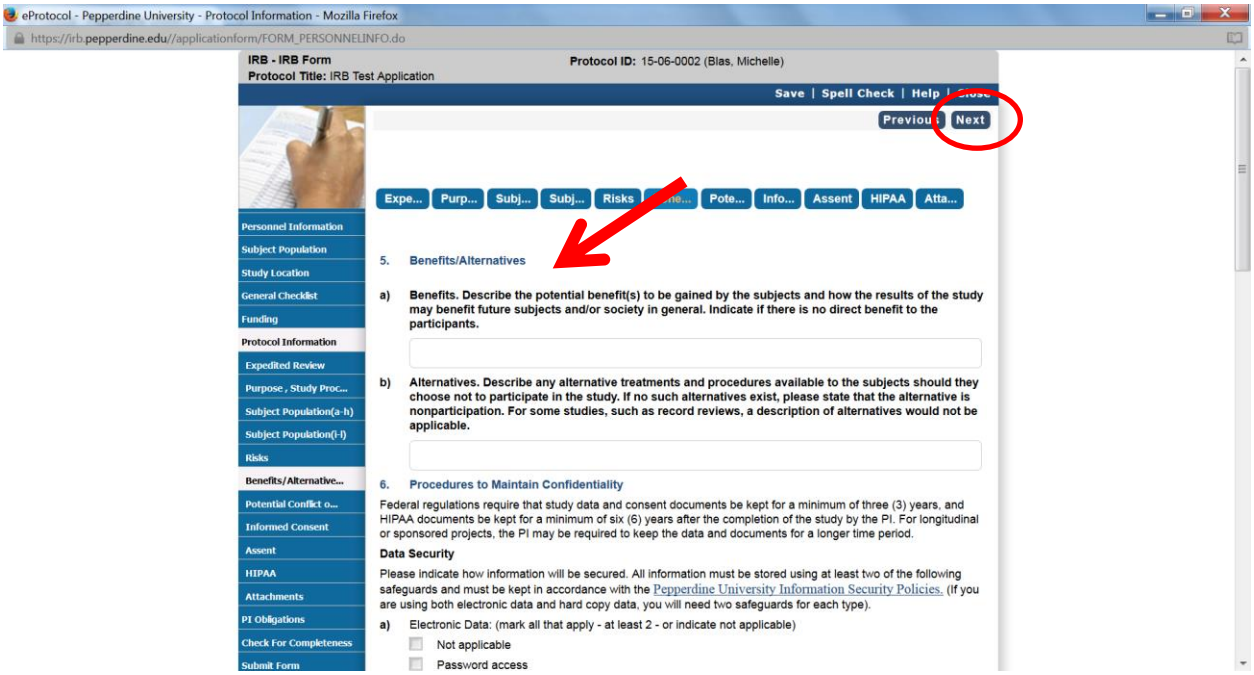
Subject Population Section continued… Answer all questions related to inclusion and exclusion criteria, compensation, and duration of the study. Click **Next** on the top, right to proceed to the next page.



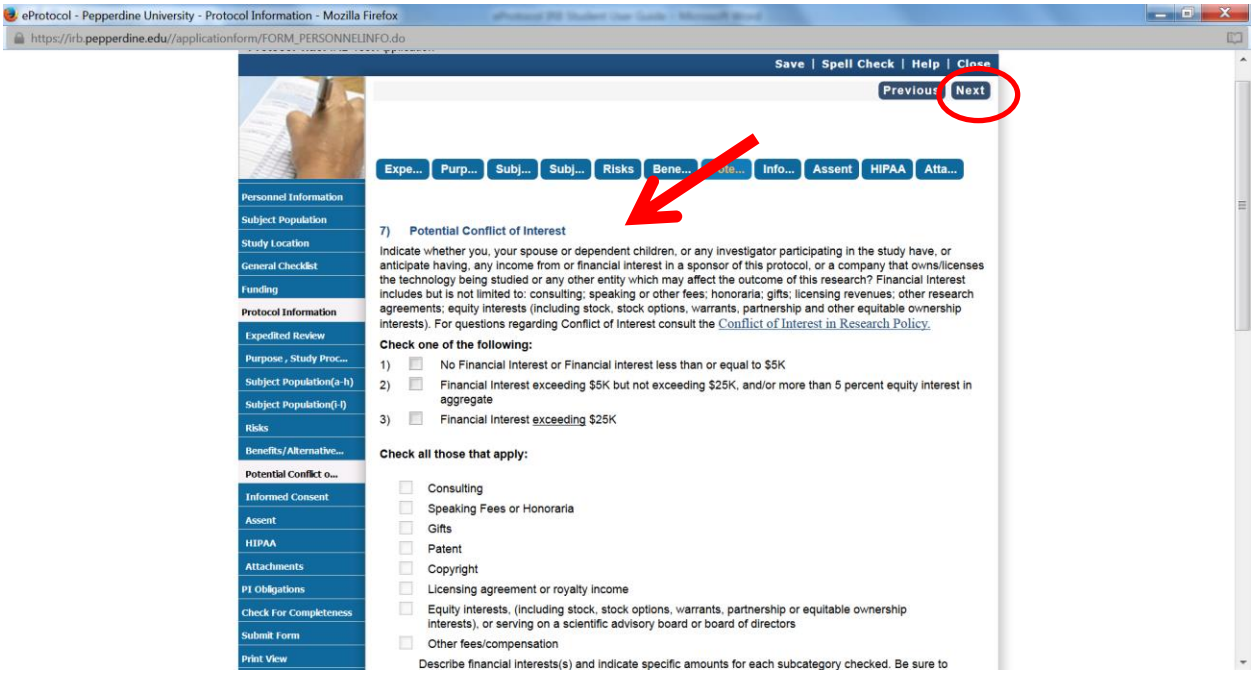
Answer all questions related to **Risks**. Click **Next** on the top, right to proceed to the next page.



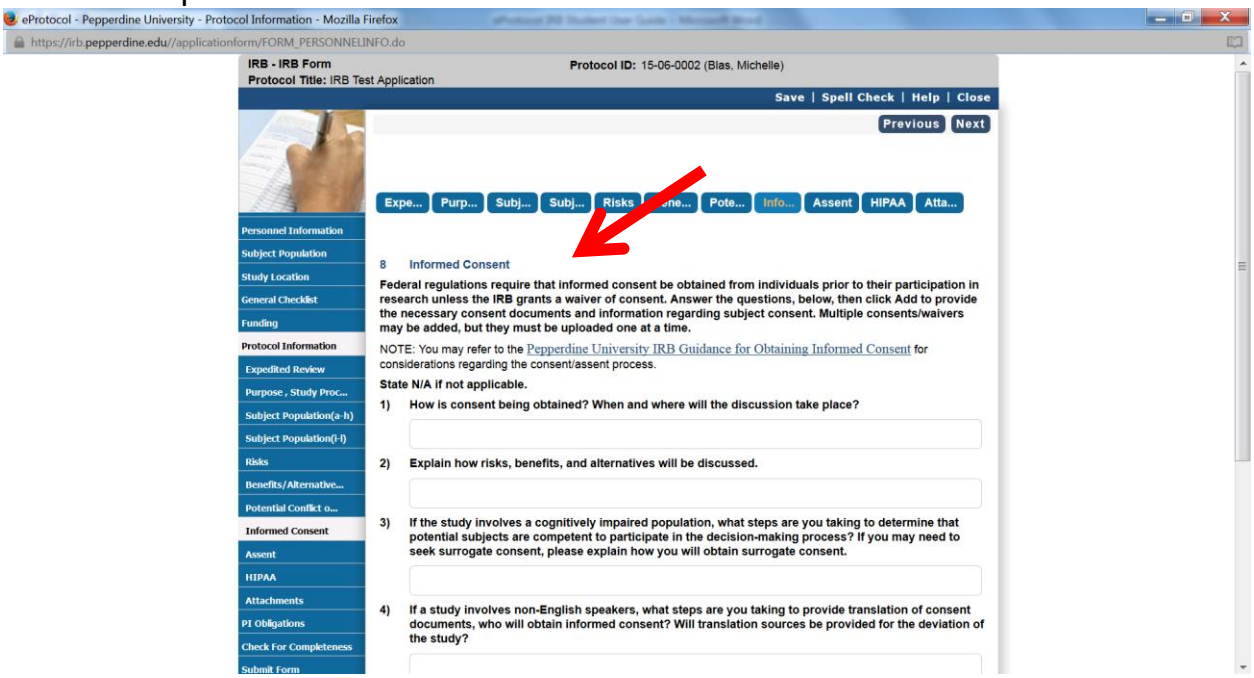
Answer all questions related to **Benefits and Alternatives**. This section also includes procedures to maintain confidentiality. Click **Next** on the top, right to proceed to the next page.



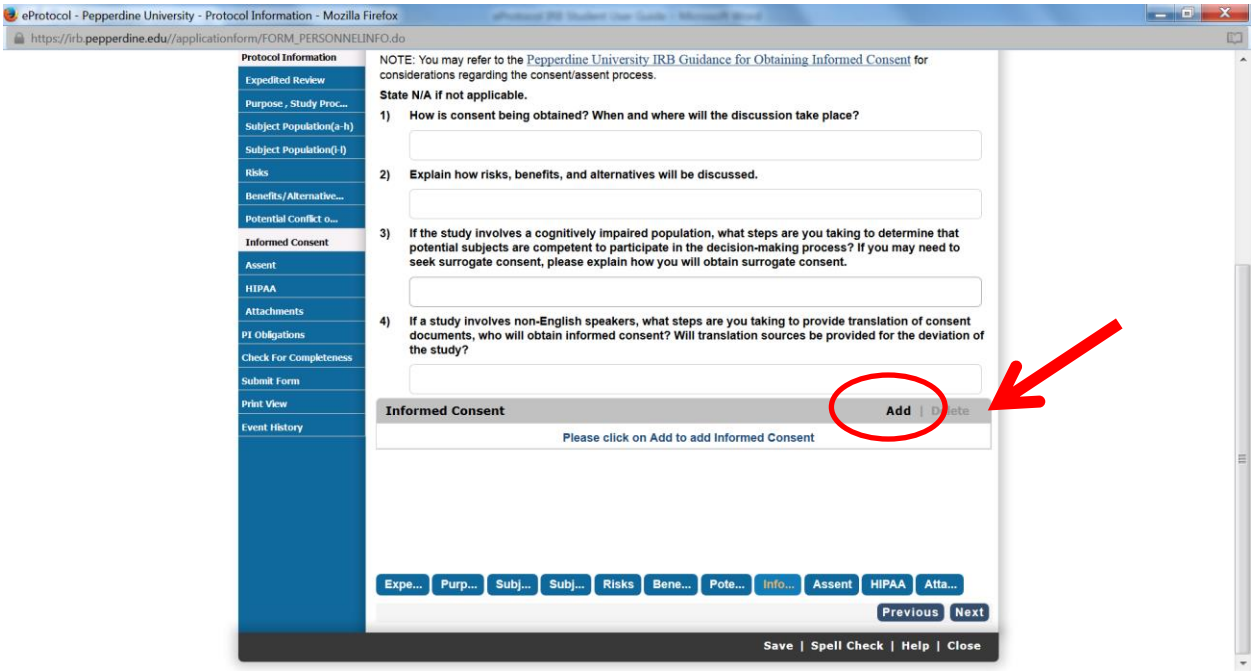
Answer all questions related to **Potential Conflict of Interest**. Click **Next** on the top, right to proceed to the next page.



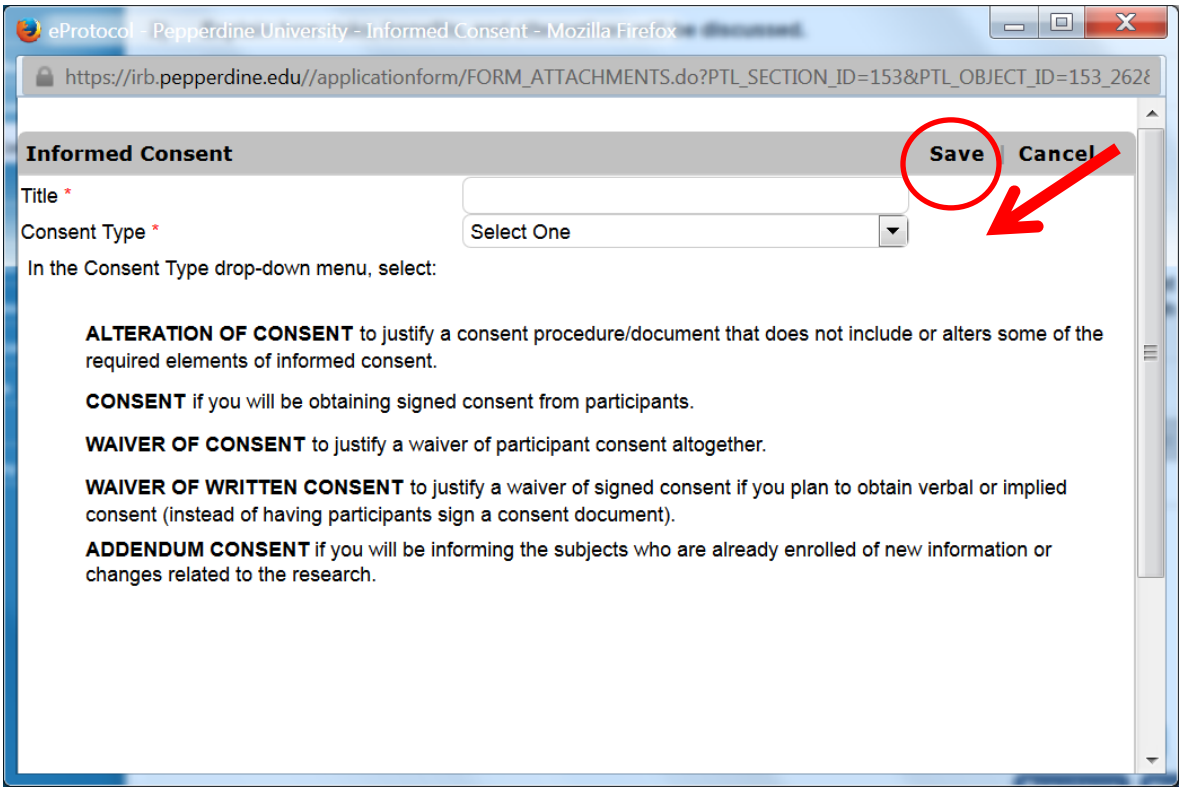
Answer all questions related to **Informed Consent**.



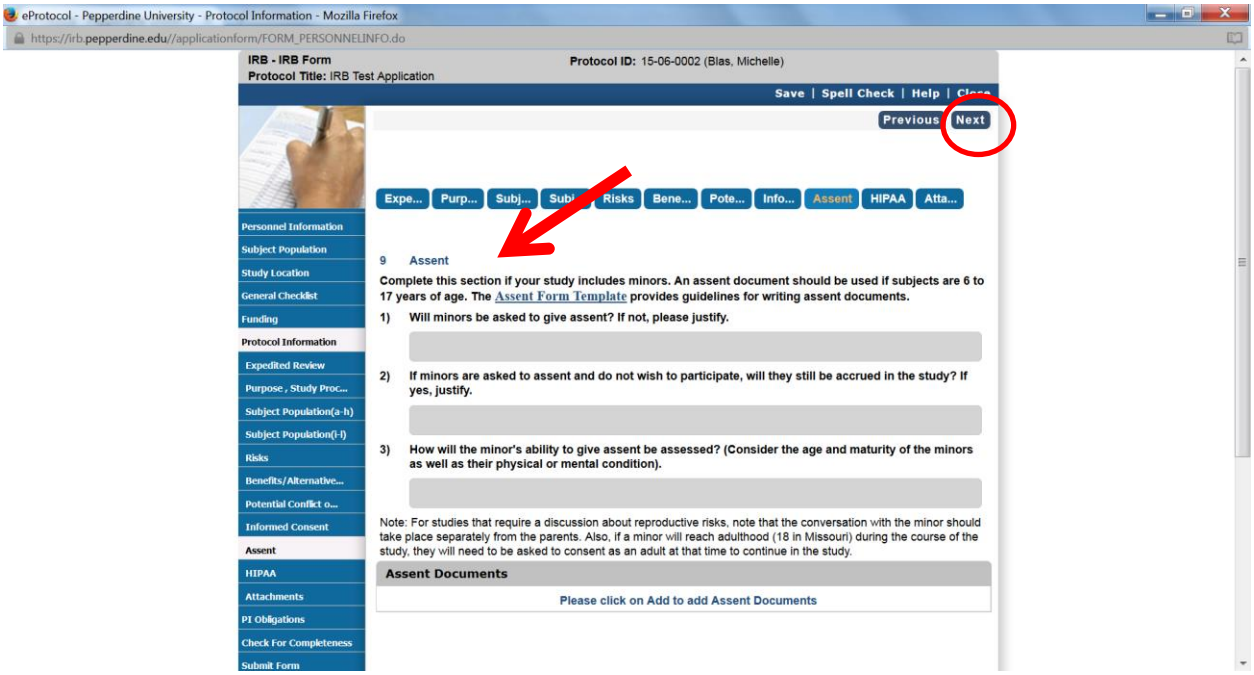
***Add your consent forms to this section of the IRB application.**



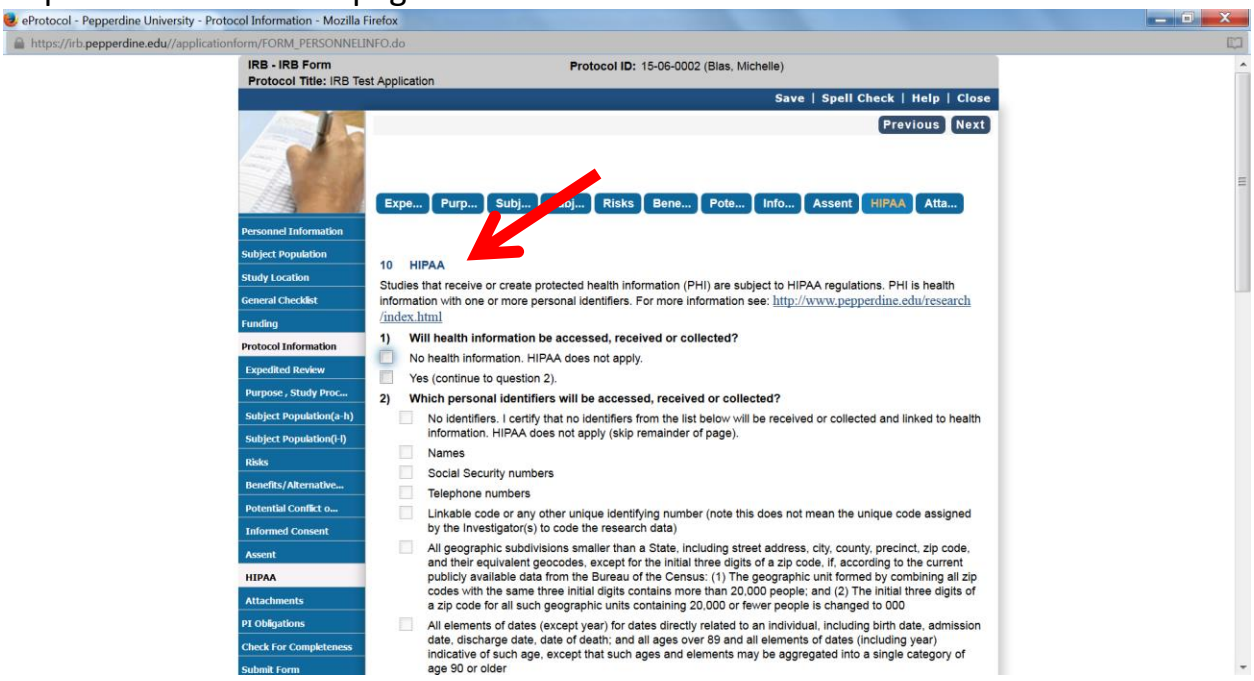
Include the type of consent form from the pull down menu. Click **Save**. Click Next on the top, right to proceed to the next page.



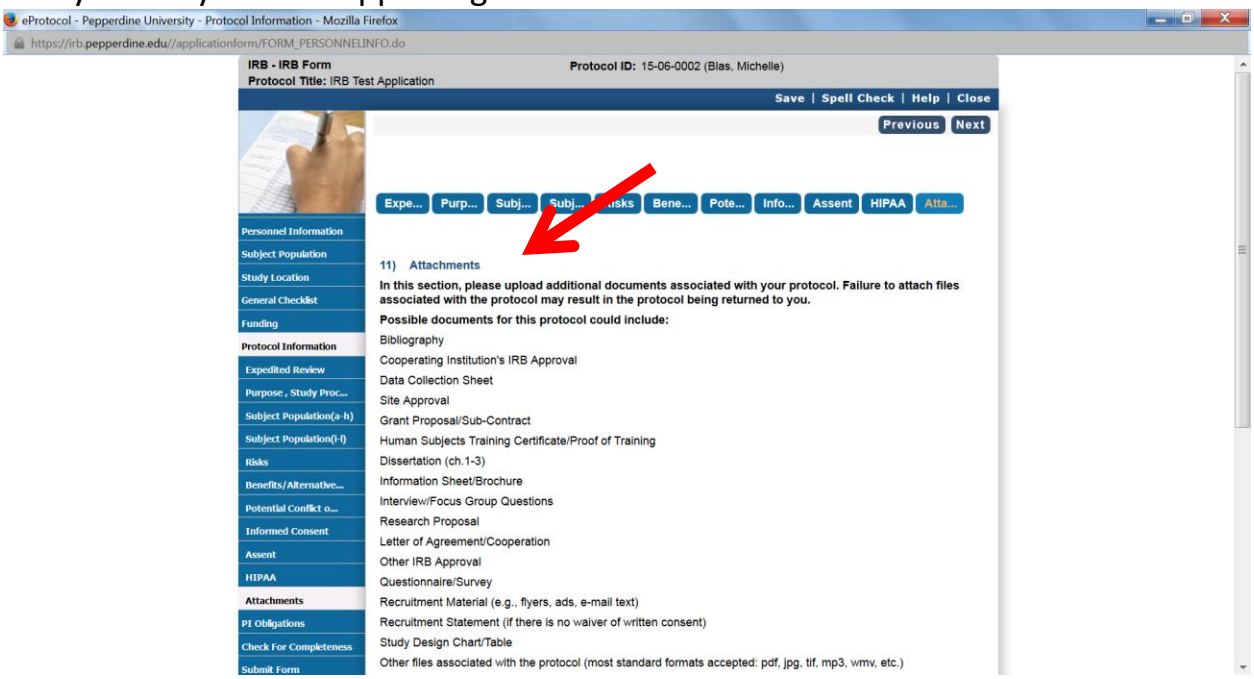
Answer all the questions related to **Assent** if there is interaction with **minors** and is applicable to the study. Add the assent documents at the end of this section and click **Save**. Click **Next** on the top, right to proceed to the next page.



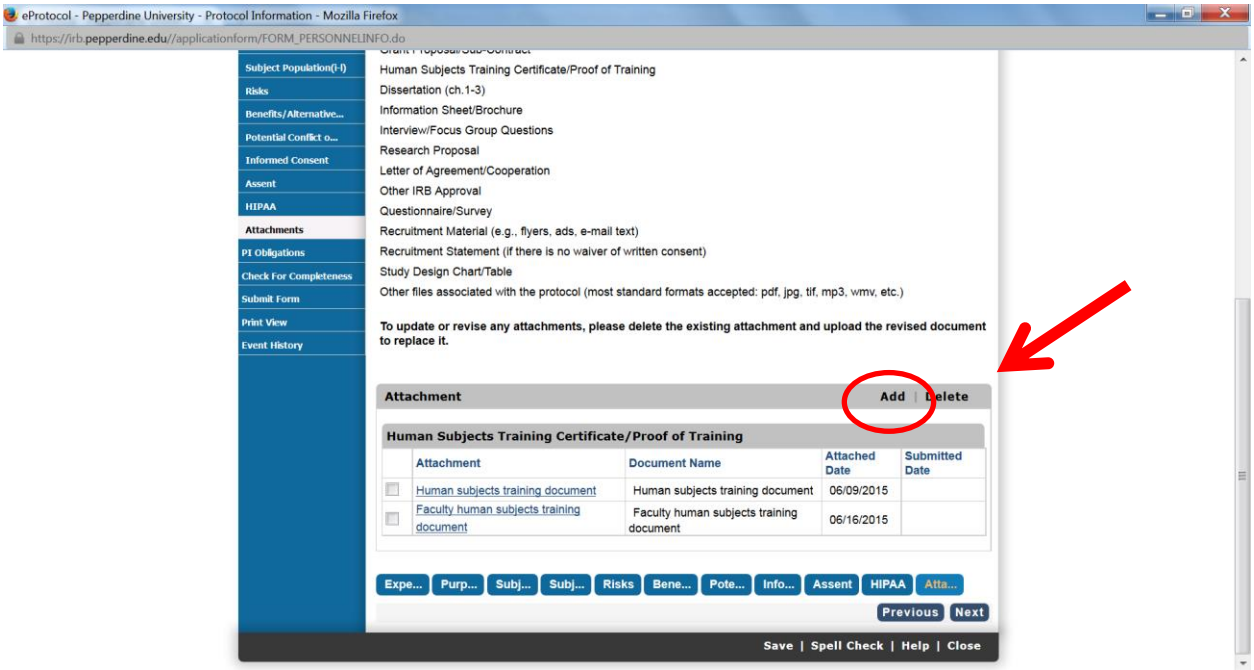
If the study is subject to **HIPAA**, complete all the answers in this section. If not, click "**No health information. HIPAA does not apply**." Click **Next** on the top, right to proceed to the next page.



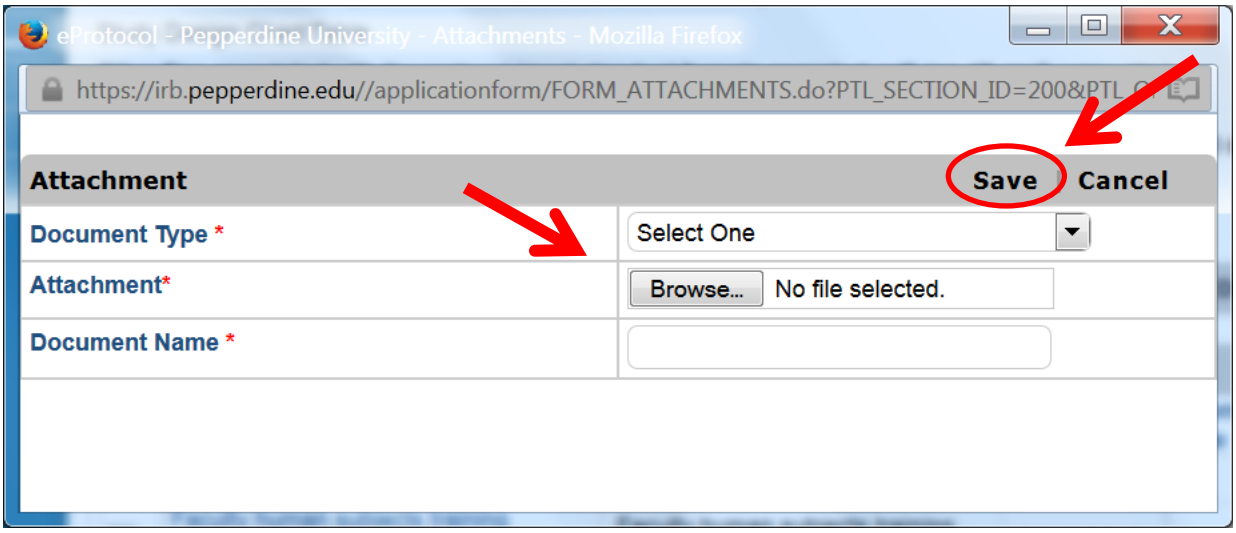
Other important **Attachments** should be added to this last section. For example, research proposal, recruitment flyers, other IRB site approvals, etc. Be sure to **clearly name the documents** so that the IRB Office and Committee members can easily identify all the supporting documents.



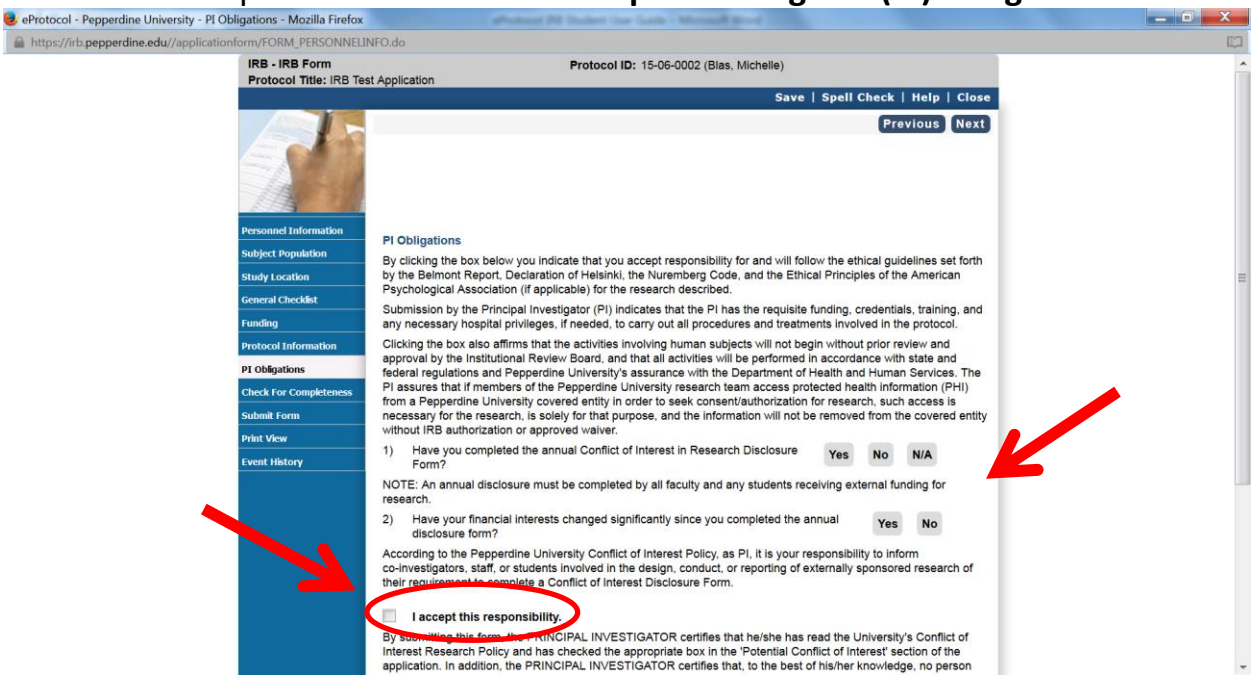
Click the **Add** button.



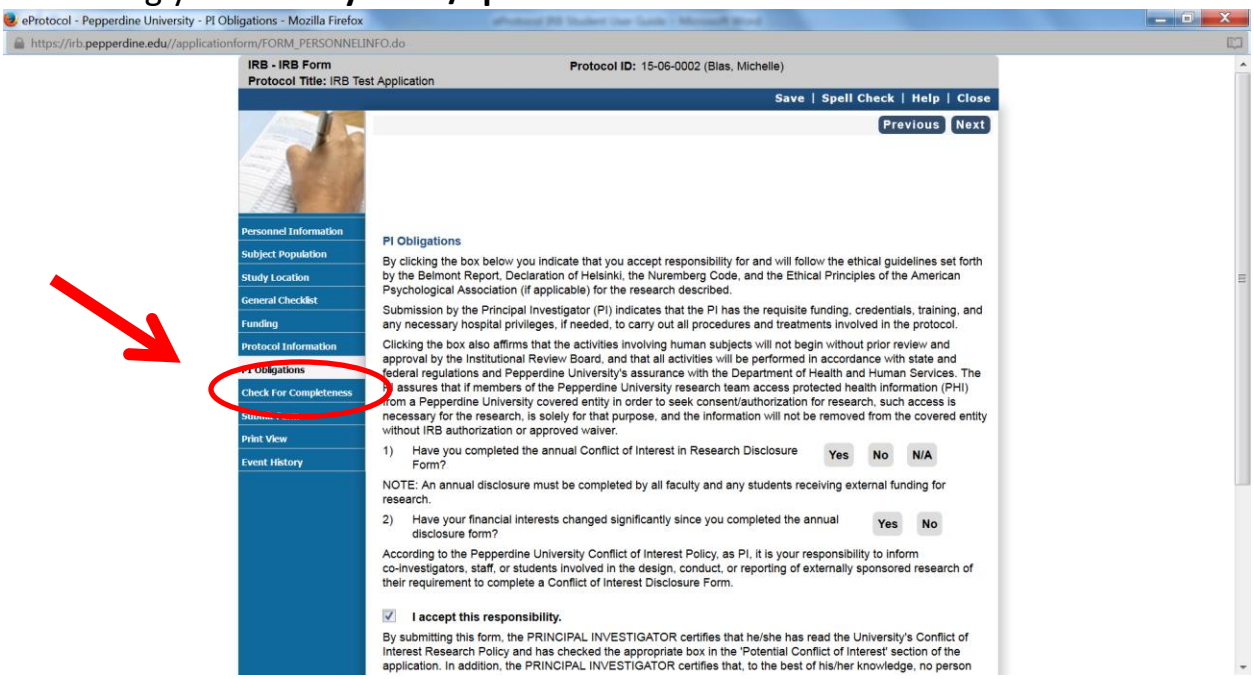
Upload the document, name the document, and click **Save**. Continue this process for all attachments.



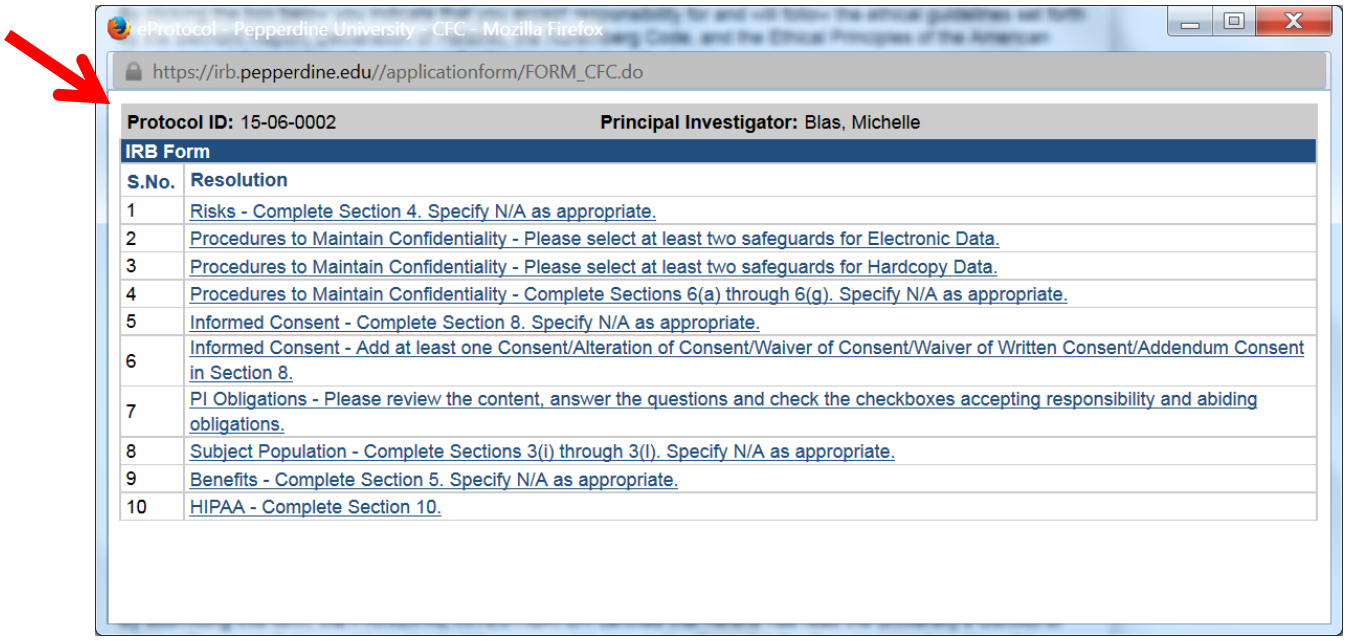
Answer all the questions related to **Principal Investigator (PI) Obligations**.



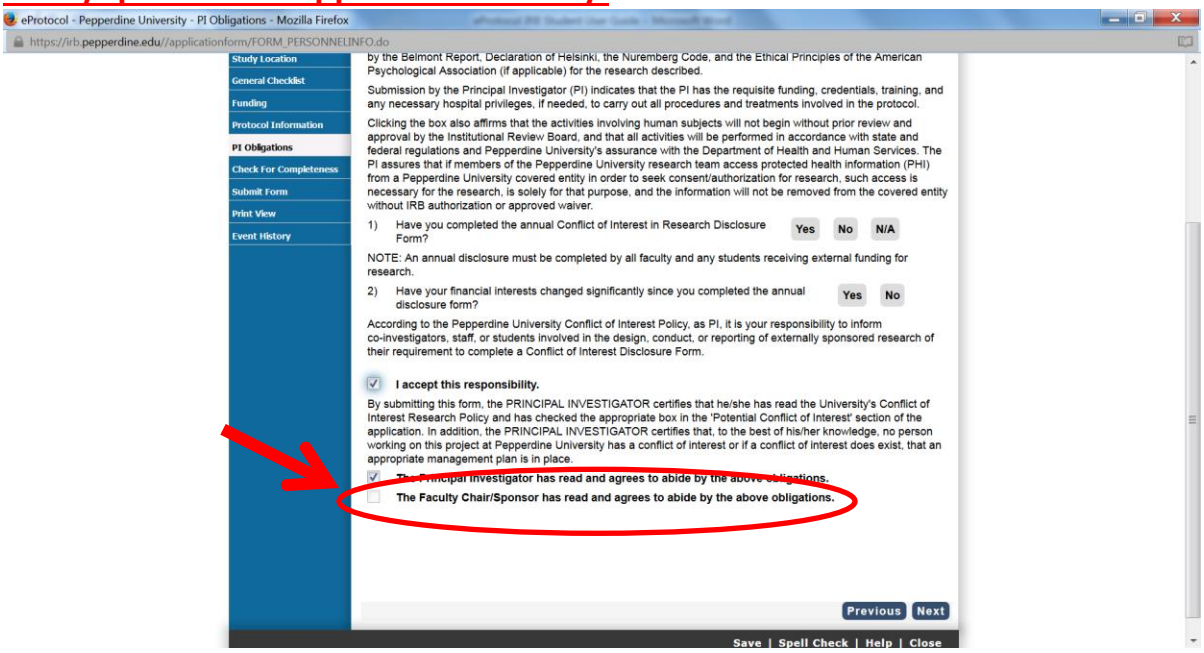
It is highly recommended to click on the **Check for Completeness** link before contacting your **Faculty Chair/Sponsor**.



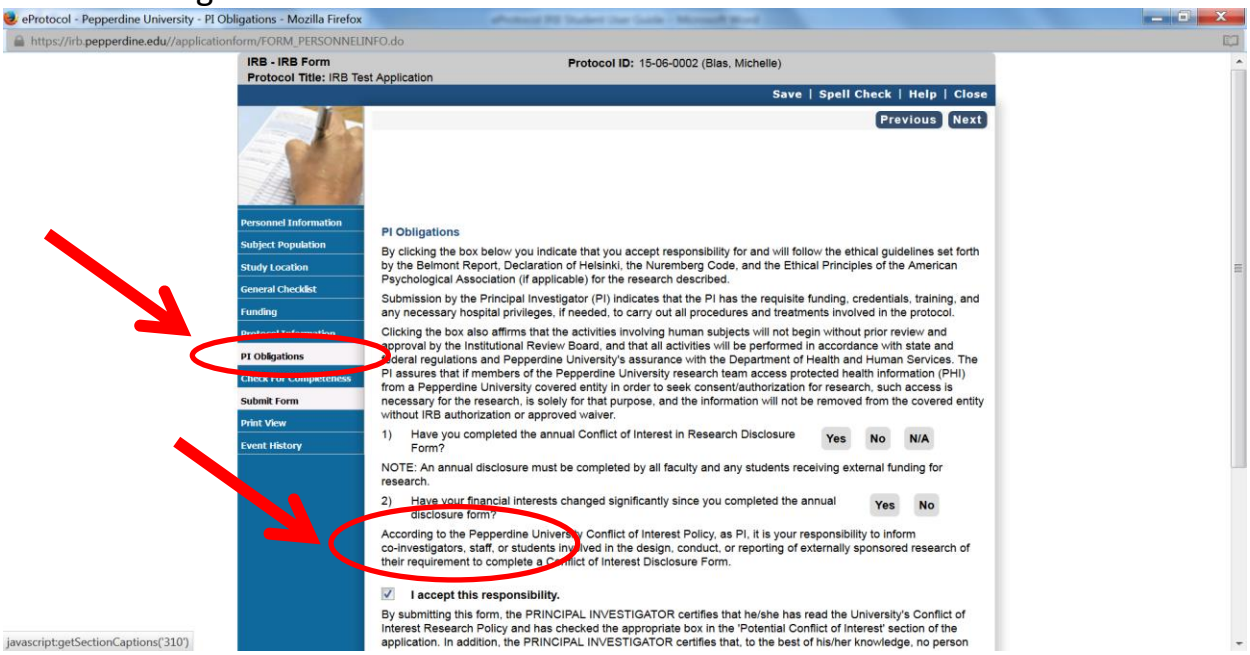
The eProtocol IRB system will identify all the sections that have missing information and need to be completed before the IRB application can be submitted to the IRB Office. All items in this section need to be cleared before being submitted to the IRB Office for review. Here's an example of missing items and how they are displayed. Click on each section and complete the missing information and click **Save**.



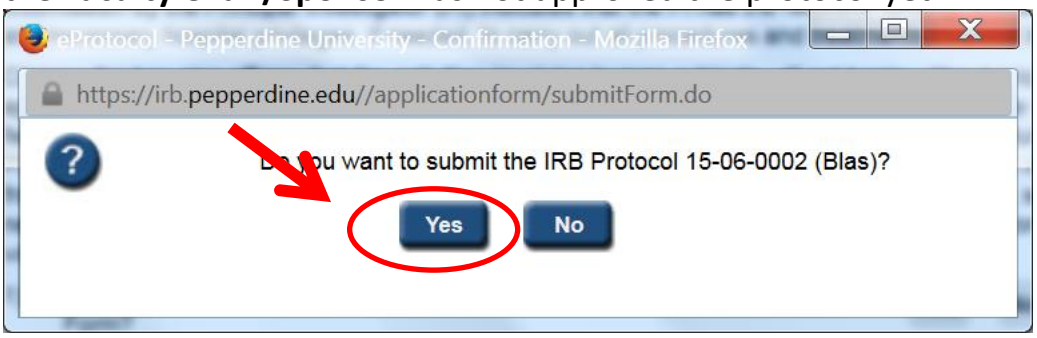
After checking for completeness, save the document and close out the IRB application window and e-mail your **Faculty Chair/Sponsor**. The Faculty Chair/Sponsor will login to eProtocol and review your application and click the statement "The Faculty Chair/Sponsor has read and agrees to abide by the above obligations." **Student Applications can only submitted after the Faculty Chair/Sponsor has approved the study.**



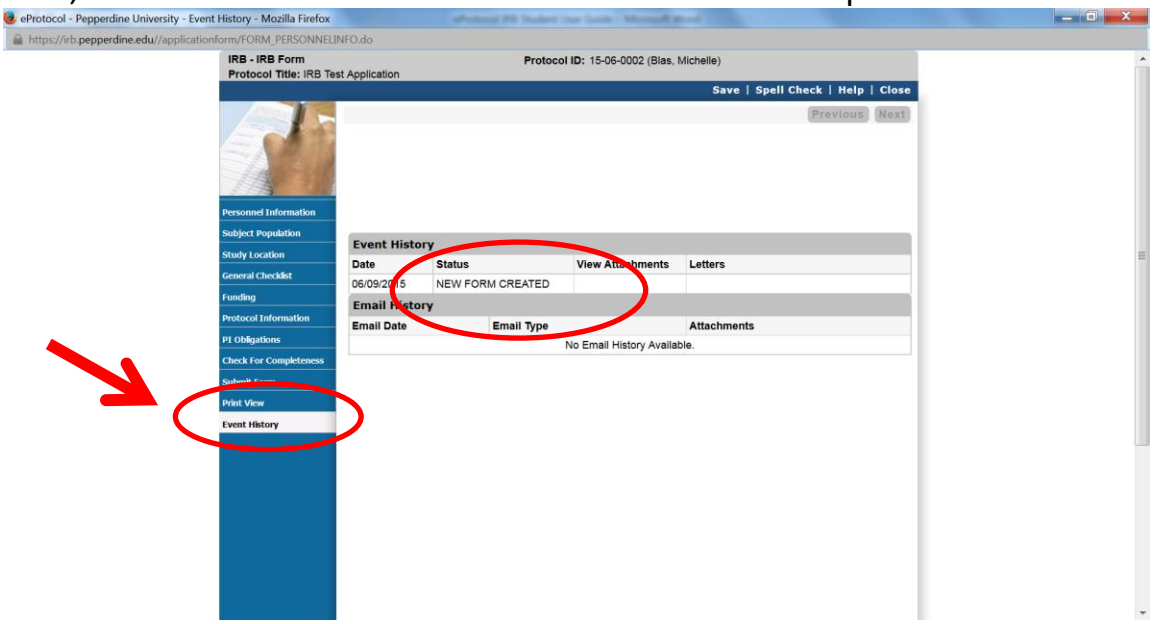
After the **Faculty Chair/Sponsor** has approved the IRB application, submit the IRB application by clicking the **Submit Form** button. Be sure to check the box to agree to the PI obligations.



After selecting the **Submit Form**, you will be directed to this screen. Click **Yes**. If you get an error message there is missing information in the IRB application or the **Faculty Chair/Sponsor** has not approved the protocol yet.

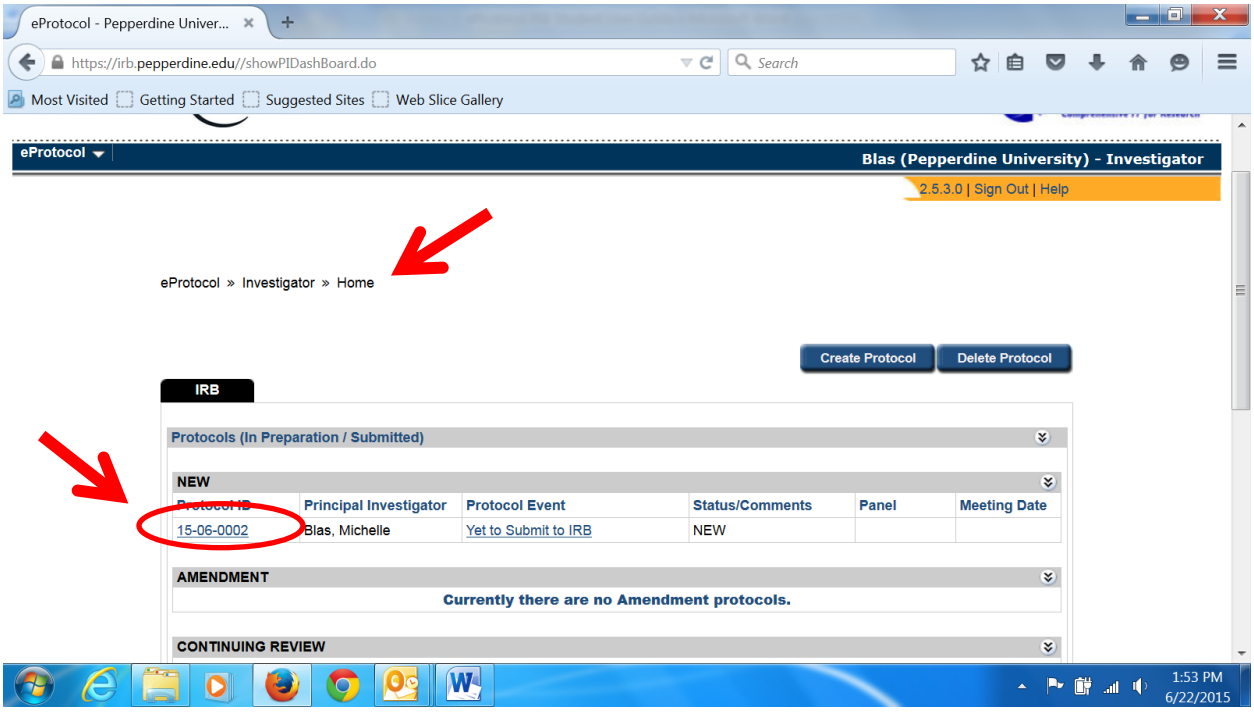


Go to **Event History** to determine if the study is still pending or submitted. In this case, it has been created and not submitted as an example.

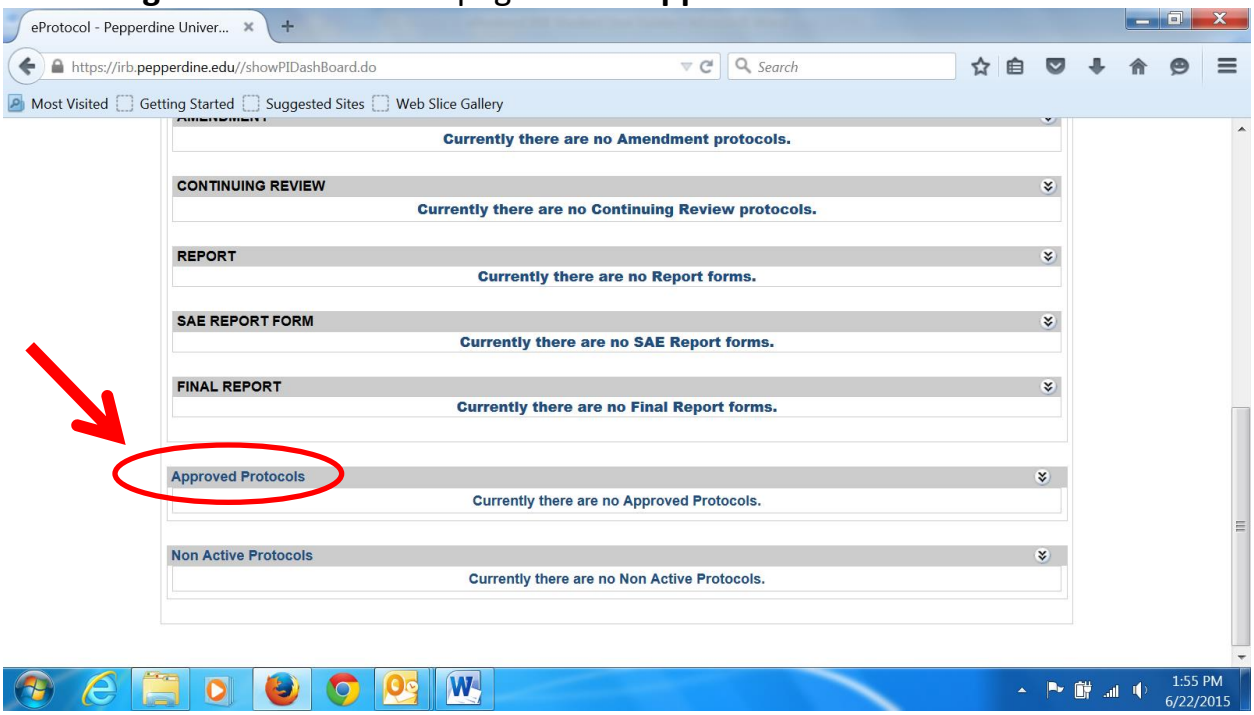


After submission, the IRB Office will review the IRB application for completeness. If there are any missing items or lacks content, the IRB application will be returned. If the application is completed, it will proceed to the IRB Committee for review.

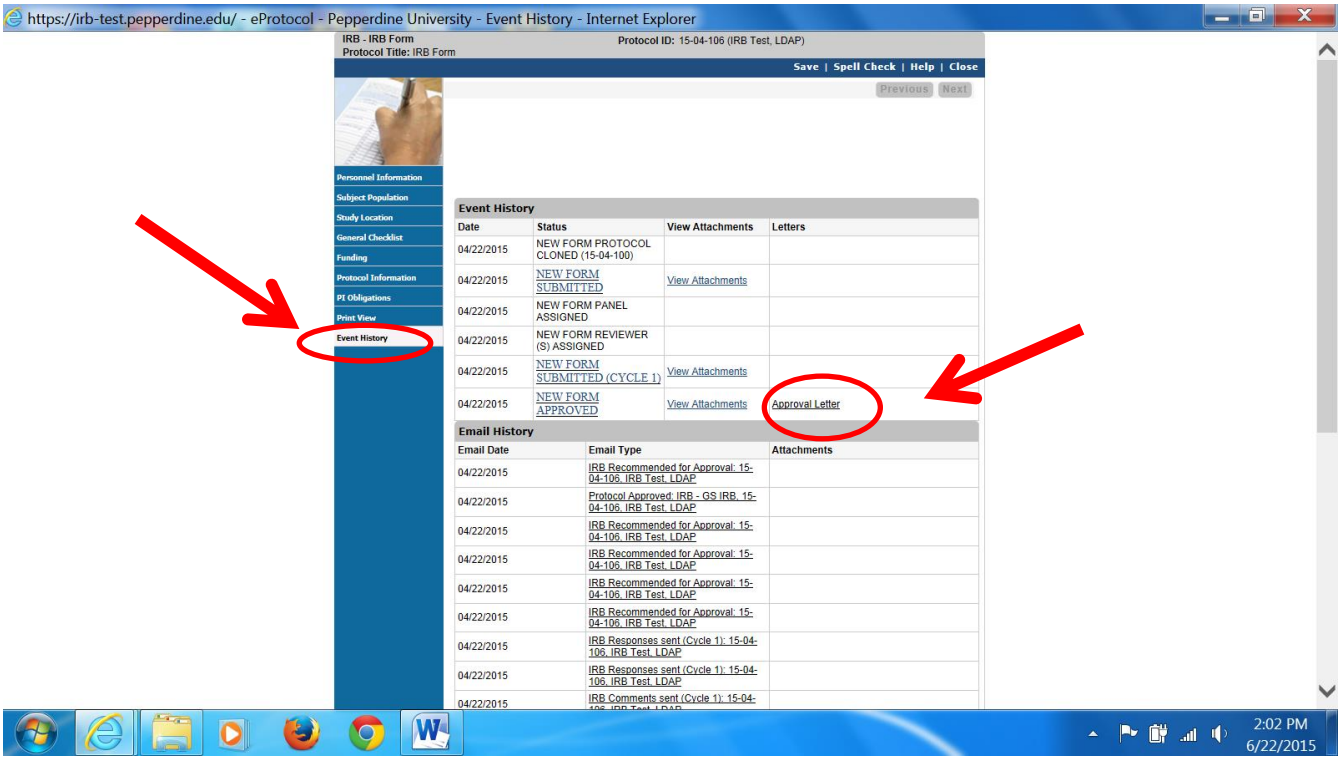
E-mails will be sent to the student for each major event in the IRB review process. To check the status of the IRB application, go to the **Investigator Home Page** and click on the **Active Protocol** and go to **Event History**.



When the IRB application has been approved, it will appear on the **Investigator Home Page** further down the page under **Approved Protocols**.



An e-mail notification will be sent when the IRB application has been approved. Login to the system at **https://irb.pepperdine.edu**. Click on the correct **Protocol** (IRB application) and select the **Event History** to retrieve the approval letter.



Other important features of the eProtocol IRB System

Amendment/Modifications

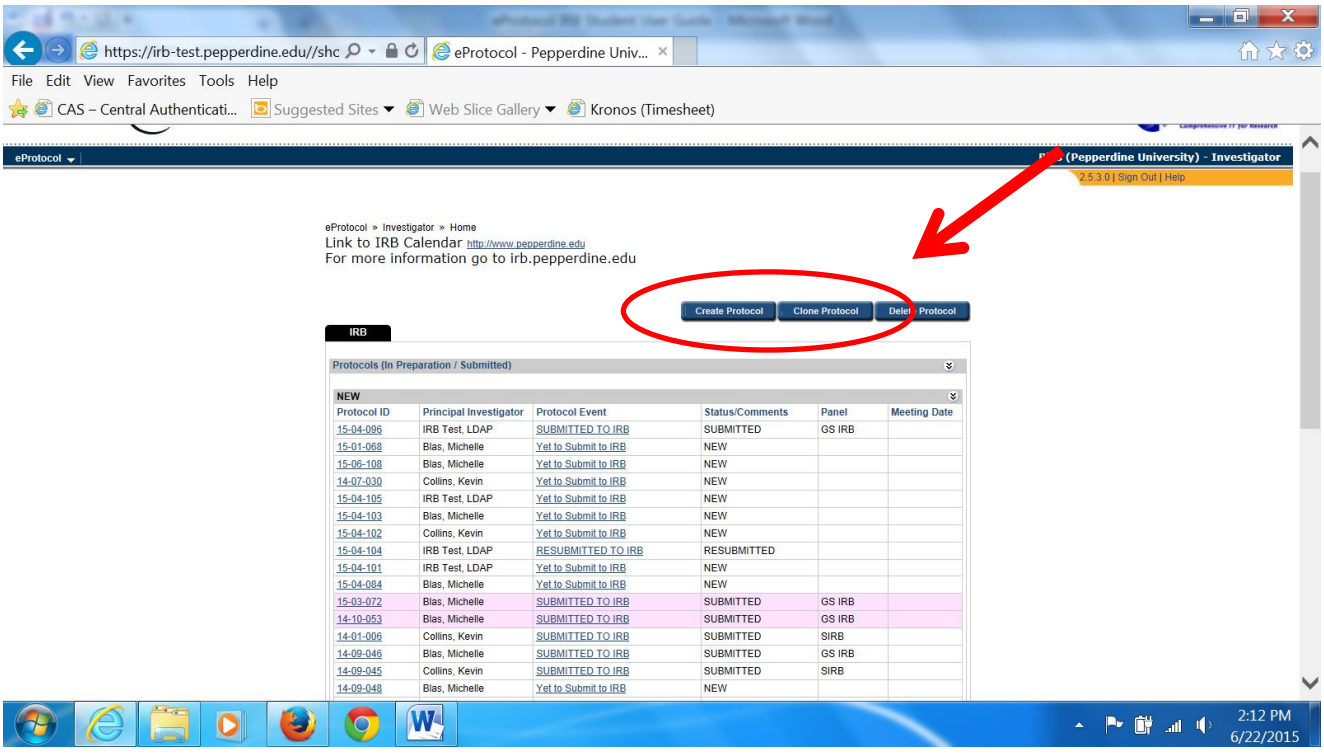
To make changes to an IRB application that has already been submitted, submit an amendment or modification and wait for IRB approval before implementing the change.

Continuing Review

Federal regulations require an IRB to conduct continuing reviews at least annually. A continuing review application should be submitted at least 1 – 2 months prior to the expiration date of the protocol to allow time for the IRB Office and IRB Committee to process and review the IRB application.

Delete/Clone Applications

In the **Investigator Home Page**, IRB applications can be cloned or deleted as needed.



Thank you for using the eProtocol IRB system at Pepperdine University.

Glossary of Terms

Administrative Contact: An individual that is noted on the IRB application (protocol) and has full access to the application.

CAS: Central Authentication Service. All Pepperdine users utilize this single, sign-on process when accessing University systems (example, WaveNet).

Faculty Chair/Sponsor: All students are required to have a faculty chair/sponsor when conducting research at Pepperdine University.

HIPPA: The Health Insurance Portability and Accountability Act (HIPPA) of 1996 is a Federal law that provides safeguards to protect the health information of individuals obtaining healthcare in the USA, also known as the Privacy Rule.

Human Subject Training Certificate: All Pepperdine students, faculty, and staff conducting research must submit a human subject training certificate. The certificate is good for 3 years and must be renewed. For more information about human subject training, go to http://community.pepperdine.edu/irb/.

Protocol: The protocol is the IRB application that is submitted. All protocols have unique identification numbers in the eProtocol IRB system.

Site location: https://irb.pepperdine.edu