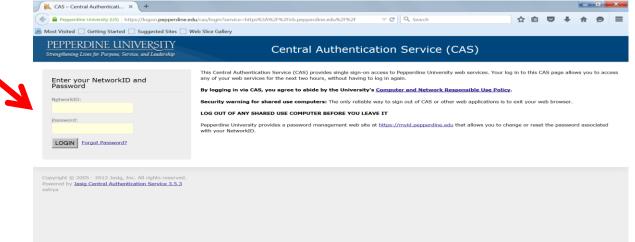
Pepperdine University eProtocol - IRB Student Investigator User Guide

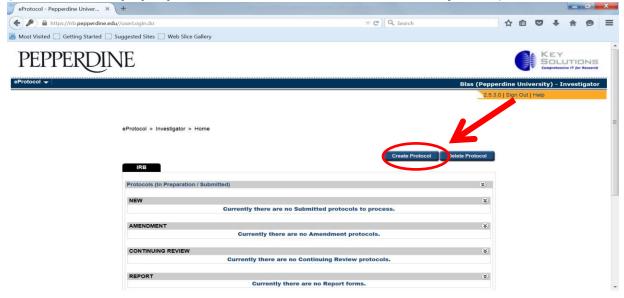
Welcome to eProtocol the online IRB system for Pepperdine University.

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

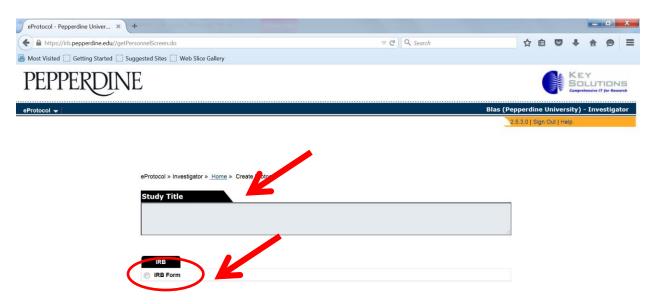
All Pepperdine student users will use their Pepperdine network ID and password through the Central Authentication Service (CAS) system. Recommended browsers include: **Internet Explorer, Safari, and Firefox**. For a glossary of terms, reference page 22 of this user guide.



After login, the IRB system will direct you to the **Investigator Home Page** to create the IRB application. Click the <u>Create Protocol</u> 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 <u>Create</u> 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.

| | | | | | | | - |
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| ← ▲ https://irb.pepperdine.edu//getPersonnelScreen.do | | ▼ C Q Search | ☆ 🖻 | ÷ | A | ø | ≡ |
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| | | | | | | | ^ |
| IRB | | | | | | | |
| IRB Form | | | | | | | |
| | | | | | | | |
| Principal Investigator* Mandat | | | | | | | |
| Pl must be Pepperdine University aff | | | | | | | |
| Name of Principal Investigator (Faculty, | | Title* | | | | | |
| | | | | | | | |
| Blas, Michelle | | | | | | | |
| Email* | Phone* | Fax | | | | | |
| | | | | | | | |
| School * | Division | | | | | | |
| Select One | Select One | | | | | | |
| | | | | | | | |
| Administrative Contact | | | | | | | - |
| Name an Administrative Contact if so | | | | | | | = |
| Name of Administrative Contact * | Degree (MD/PhD/Other) | Title* | | | | | |
| - A A A A A A A A A A A A A A A A A A A | | | | | | | |
| Email* | Phone* | Fax | | | | | |
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| School* | Division | | | | | | |
| Select One | Select One | | | | | | |
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The **Principal Investigator** information that was entered in the previous page will carry over to the IRB application. Select your status as a <u>Student</u> and click <u>Yes</u> for completing human subjects training. (This is a requirement for all IRB applications to be processed at Pepperdine University).

| sonnel Information - Mozilla | a Firefox | abort One Lants Marcall Blord | | |
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| IRB - IRB Form | Pi | rotocol ID: 15-06-0002 (Blas, Michelle) | | |
| Protocol Title: IRB Te | est Application | - | | |
| | | S | ave Spell Check Help Close | |
| | | | Previous Next | |
| 7/23/ | | | | |
| Personnel Information | Study Personnel Roles: | | | |
| Subject Population | -Principal Investigator: accepts respo | | | |
| Study Location | Administrative Contact: additional st of research team | udy contact, can edit/prepare protocol, | may or may not also be member | |
| General Checklist | -Key Personnel (Research Team): Pe | epperdine University member of researc | h team, can view protocol (not | |
| Funding | edit) -Non-Pepperdine Collaborator: mem | ber of research team from another instit | tution or organization outside of | |
| Protocol Information | Pepperdine University, has no access t | | | |
| PI Obligations | IMPORTANT NOTE: Human Subjects | Protection Training is mandatory for all | research team personnel. | |
| | Principal Investigator* Mand | atory | | |
| | PI must be Pepperdine University a | ffiliate. | | |
| | Name of Principal Investigator (Faculty, Staff or Student)* | Degree (MD/PhD/Other) | Title* | |
| | Blas, Michelle | | Director | |
| | Email* | Phone* | Fax | |
| | Michelle.Blas@pepperdine.edu | 310-568-5735 | | |
| | School * | Division | | |
| | Graduate School of Education an | Education | | |
| | Please indicate your status * | | Select One | |
| | Human Subjects Training Complete | d? * | Yes No | |

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.)

| Adocol - Pepperdine University - Personnel Information - Mozilia | THEIOX | | | | | | |
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| ps://irb. pepperdine.edu //applicationform/FORM_PERSONNEL | NFO.do | | | | | | |
| | Graduat | e School of Education an | Education | | | • | |
| | Please in | dicate your status * | | | | Select One | |
| | | | | | | | |
| | | | - 10 - | | | | |
| | | Subjects Training Complete | | | | No | |
| | If you ha | tachments section. | is not auto-popula | ited be | low, u | bload a copy Add | |
| | Research | n Team Member Duties Pic | klist* |) | | | |
| | 1. | Pecruitment | | 2. | | Obtains consent | |
| | 3. | Determine Subject Elig | gibility for Accrual | 4a. | | Subject Physical Examinations | |
| | 4b. | Follow-up Visits includ assessments | ding physical | 5. | | Perform study procedures or Specimen Collection | |
| | 6a. | Administer and/or Dis Drugs, Biologics or De | | 6b. | | Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices | |
| | 7. | Subject Randomizatio | n or Registry | 8. | | Collection of Subject Data | |
| | 9. | Report Data (CRFs, e- Spreadsheets) | CRFs, | 10. | | Data Analysis | |
| | 11a. | Review Adverse Event | ts | 11b. | | Treat and Classify Adverse Events | |
| | 12. | Other (Please insert e) | xplanation below.) | | | | |
| | | | | | | | |
| | | | No training d | ata is a | vailabl | a. | |
| | Facult | y Chair/Sponsor* Man | datory | | | Clear | |
| | | Faculty Chair/Sponsor* | Degree (MD/PhD | (Other) | | Title* | |
| | | , | | | | | |
| | Email* | | Phone* | | _ | Fax | |
| | School * | | Division | | | | |
| | Select C |)ne 🔻 | | | | • | |

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 <u>Save</u> button.

| eProtocol - Pepperdine University - Attachments - M | ozilla Firefox |
|---|--|
| https://irb.pepperdine.edu//applicationform/FORM | 1_ATTACHMENTS.do?PTL_SECTION_ID=200&P7.2 |
| Attachment | Save Cancel |
| Document Type * | Select One |
| Attachment* | Browse No file selected. |
| Document Name * | |
| | |
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| | |

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 <u>Next</u> on the top, right to proceed to the next page.

| | No training data is available. | | |
|---|---|------------------|---|
| Faculty Chair/Sponso | r* Mandatory | Clear | |
| Name of Faculty Chair/Spo | nsor* Degree (MD PhD/Other) | Title* | |
| Email* | Phone* | Fax | |
| School * | Division | | |
| Select One | ▼ Select One | • | |
| is the (Role) also a Departr | nent Chair? | Yes No | |
| Human Subjects Training C | Completed? * | Yes No | • |
| If you have completed train in the Attachments section | ning that is not auto-populated below, uple | oad a copy | |
| Faculty advisor/mentor is a | a member of the study* | Yes No | |
| | No training data is available. | | |
| Administrative Contac | | Add Delete | |
| | Please click on Add to add Administra | tive Contact | |
| Key Personnel (Resear | • | Add Delete | |
| P | lease click on Add to add Key Personnel | Research Team) | |
| Non - Pepperdine Colla | | Add Delete | |
| | Please click on Add to add Non - Pepperd | ine Collaborator | |
| | | | |

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

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| | Personnel Information | | | _ |
| | Subject Population | Su | oject Population(s) Checklin | |
| | Study Location | | Select All That Apply: | E |
| | General Checklist | | Adult Volunteers | |
| | Funding | | Cognitively Impaired Subjects | |
| | Protocol Information | | Employees | |
| | PI Obligations | | Fetuses | |
| | | | Minors (under 18) | |
| | | | Pregnant Women | |
| | | | Prisoners | |
| | | | Students | |
| | | 100 | Terminally III Subjects | |
| | | 100 | Wards of the State | |
| | | 122 | Non-English Speakers | |
| | | 10 | Other (any population that is not specified above) | |
| | | | | |
| | | | | |
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| | | | | * |

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 <u>Next</u> on the top, right to proceed to the next page.

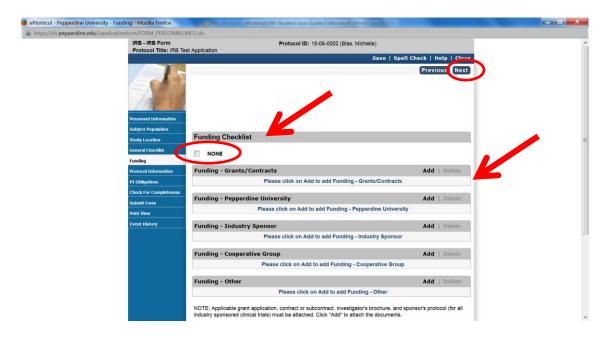
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| | IRB Form Protocol ID: 15-06-0002 (Blas, Michelle) | • |
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| | Net Information Propulation Study Location(s) Checklist | |
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| General | Checklist Encino Campus | |
| Funding | | |
| Protoco | I Information Malibu Campus | |
| PI Oblig | ations 🔲 West Los Angeles Campus | |
| | Westlake Village Campus | |
| | Other (In the box below, list any off-campus institutions or locations and describe the activities being conducted there. Please provide letters of cooperation and/or IRB approvals from each location to document support/approval of the study. You may provide such documentation as it becomes available, but you may not begin work at those sites until documentation of support is provided to the IRB). | |
| | Other Pepperdine University sites (in the box below, list any other on-campus locations) | |
| | | |

Select the type of study (exempt, expedited, non-human subjects, etc.). Select all that apply. Click <u>Next</u> 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.

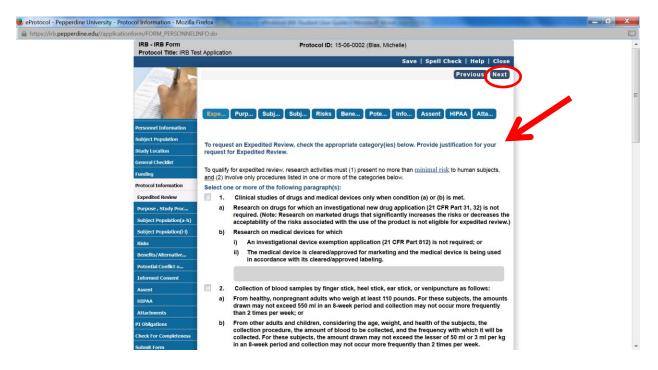
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| | Personnel Information Subject Population | | | |
| | Second Second Second | Gei | neral Checklist | |
| | Study Location | | Select All That Apply : | |
| | General Checklist | | Study Eligible for Expedited Review | |
| | Funding | | Study Eligible for Exempt Review | |
| | Protocol Information | E | Non-human subjects research | |
| | PI Obligations | | Collection of Specimens | |
| | | | Data collection via e-mail or the Internet | |
| | | | Data Collection via Interviews | |
| | | | Genetic Testing | |
| | | | Human blood, cells, tissues, or body fluids | |
| | | | Investigational drugs, reagents, chemicals, or biologic products | |
| | | | Investigational Device | |
| | | | Investigator Initiated Study | |
| | | | Medical Records | |
| | | | Photography, Video, or Voice-Recording Subjects | |
| | | | Questionnaires and/or tests | |
| | | | Study of existing data or specimens | |
| | | | Other (clarify in text box to the right) | |
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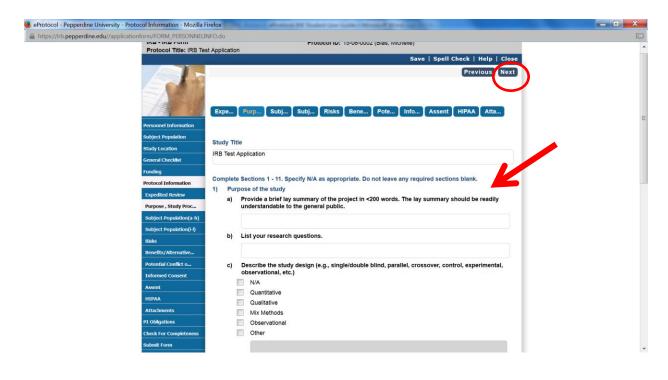
The next section inquires about funding. If the study is not funded by Pepperdine or an outside agency/organization, click <u>NONE</u>. If the research is being funded, select the category and provide the name and grant contract for review by the IRB Office. Click <u>Next</u> on the top, right to proceed to the next page.



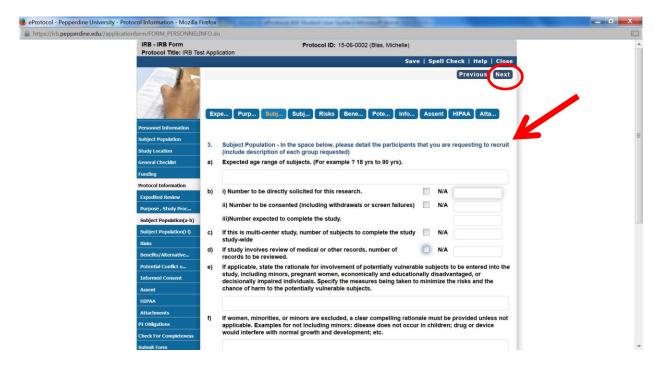
The next section starts the IRB application (**exempt or expedited**). Select the appropriate category depending on if the study is exempt or expedited. Click <u>Next</u> on the top, right to proceed to the next page.



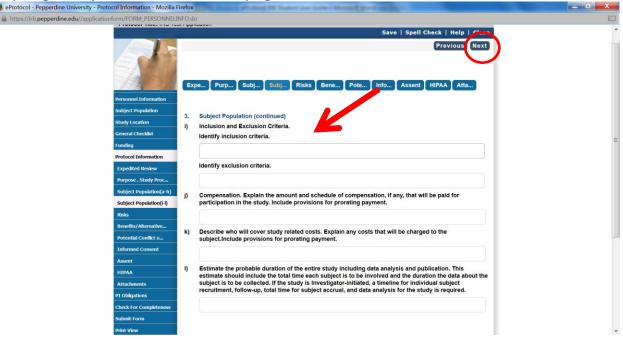
Answer all the questions in the **Purpose Section**. Click <u>Next</u> on the top, right to proceed to the next page.



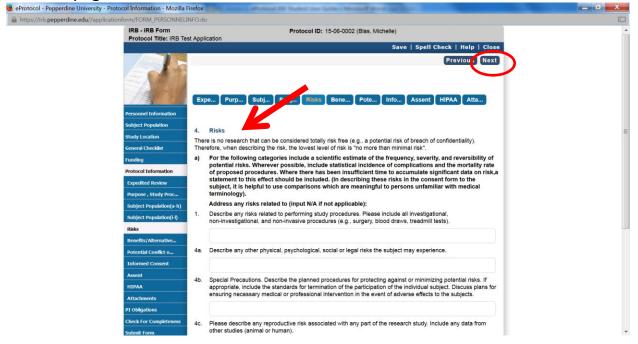
Answer all the questions about the **Subject Population**. Give details of the subjects' ages, number to directly solicit, consented subjects, etc. If non-applicable, select N/A. Click <u>Next</u> on the top, right to proceed to the next page.



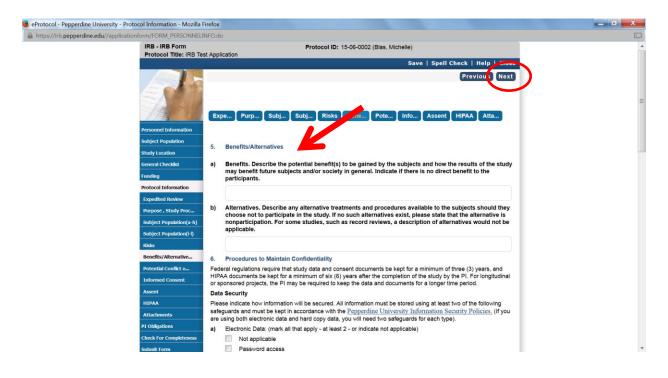
Subject Population Section continued... Answer all questions related to inclusion and exclusion criteria, compensation, and duration of the study. Click <u>Next</u> on the top, right to proceed to the next page.



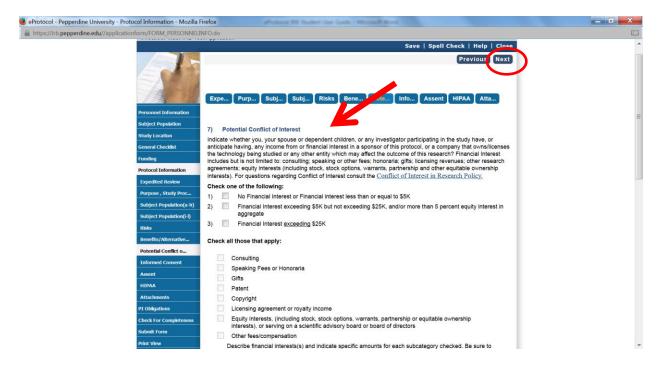
Answer all questions related to **Risks**. Click <u>Next</u> on the top, right to proceed to the next page.



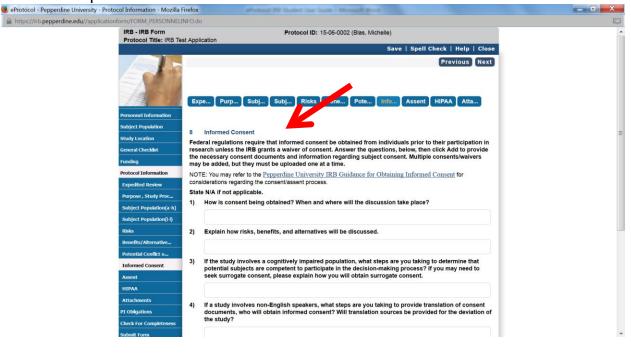
Answer all questions related to **Benefits and Alternatives**. This section also includes procedures to maintain confidentiality. Click <u>Next</u> on the top, right to proceed to the next page.



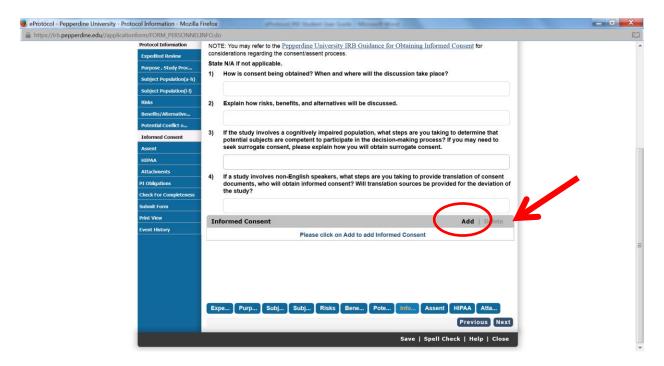
Answer all questions related to **Potential Conflict of Interest**. Click <u>Next</u> on the top, right to proceed to the next page.



Answer all questions related to Informed Consent.



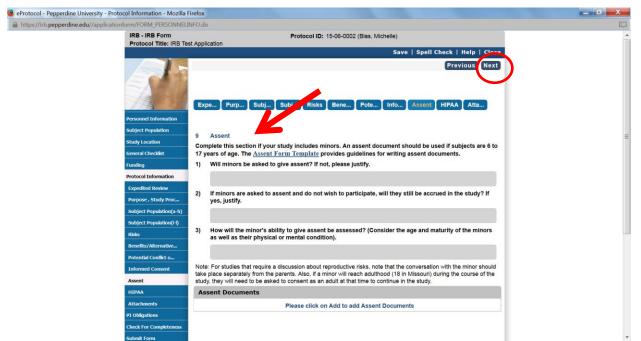
*Add your consent forms to this section of the IRB application.



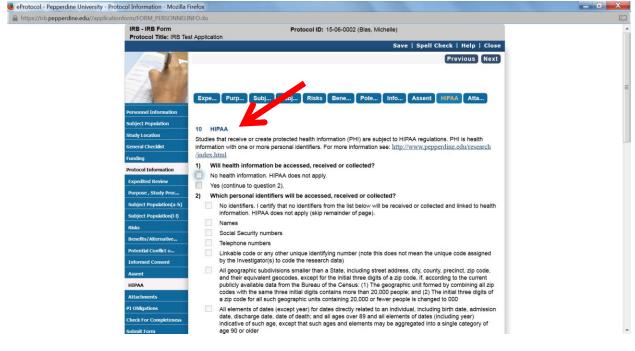
Include the type of consent form from the pull down menu. Click <u>Save</u>. Click <u>Next</u> on the top, right to proceed to the next page.

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| https://irb.pepperdine.edu//applicationform, | /FORM_ATTACHMENTS.do?PTL_SECTION_ID=153&PTL_OBJECT_ID=153_262& |
| | |
| Informed Consent | Save Cancel |
| Title * | |
| Consent Type * | Select One |
| In the Consent Type drop-down menu, select: | |
| ALTERATION OF CONSENT to justify a c required elements of informed consent. | consent procedure/document that does not include or alters some of the |
| CONSENT if you will be obtaining signed | consent from participants. |
| WAIVER OF CONSENT to justify a waive | r of participant consent altogether. |
| WAIVER OF WRITTEN CONSENT to just consent (instead of having participants sig | tify a waiver of signed consent if you plan to obtain verbal or implied on a consent document). |
| ADDENDUM CONSENT if you will be info changes related to the research. | orming the subjects who are already enrolled of new information or |
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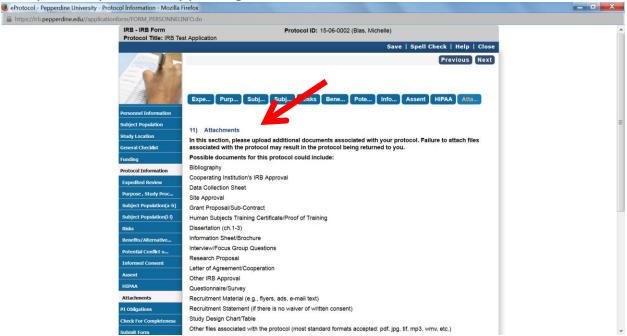
Answer all the questions related to **Assent** if there is interaction with <u>minors</u> and is applicable to the study. Add the assent documents at the end of this section and click <u>Save</u>. Click <u>Next</u> on the top, right to proceed to the next page.



If the study is subject to **HIPAA**, complete all the answers in this section. If not, click "<u>No health information. HIPAA does not apply</u>." Click <u>Next</u> 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 <u>clearly name the documents</u> so that the IRB Office and Committee members can easily identify all the supporting documents.



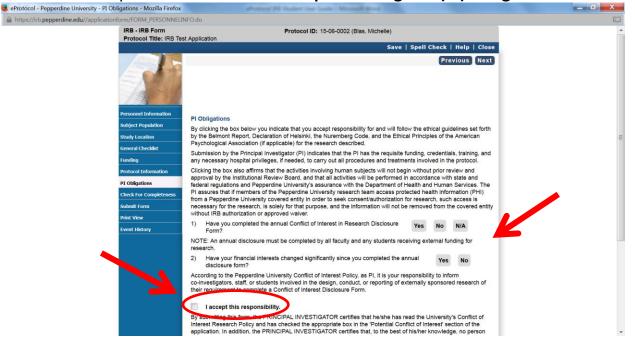
Click the Add button.

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| | Subject Population(i-I) | Human Subjects Training Certificate/Proof of | Training | | | ^ |
| | Risks | Dissertation (ch. 1-3) | | | | |
| | Benefits/Alternative | Information Sheet/Brochure | | | | |
| | Potential Conflict o | Interview/Focus Group Questions | | | | |
| | | Research Proposal | | | | |
| | Informed Consent | Letter of Agreement/Cooperation | | | | |
| | Assent | Other IRB Approval | | | | |
| | НІРАА | Questionnaire/Survey | | | | |
| | Attachments | Recruitment Material (e.g., flyers, ads, e-mail | text) | | | |
| | PI Obligations | Recruitment Statement (if there is no waiver of | of written consent) | | | |
| | Check For Completeness | Study Design Chart/Table | | | | |
| | Submit Form | Other files associated with the protocol (most | standard formats accepted: pdf, jpg, tif, | mp3, wmv, etc | .) | |
| | Print View | To update or revise any attachments, plea | se delete the existing attachment and | upload the re | vised document | |
| | Event History | to replace it. | 117 | | | |
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| | | Attachment | | Ad | d Lelete | |
| | | Attachment | | ~ | u l'urrete | |
| | | Human Subjects Training Certificat | te/Proof of Training | | | |
| | | Attachment | Document Name | Attached Date | Submitted Date | = |
| | | Human subjects training document | Human subjects training document | 06/09/2015 | | - |
| | | E Faculty human subjects training document | Faculty human subjects training document | 06/16/2015 | | |
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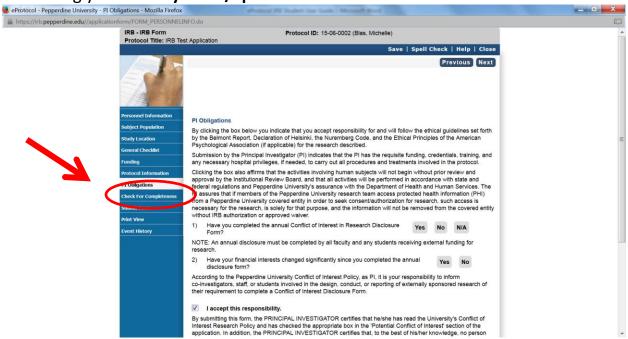
Upload the document, name the document, and click <u>Save</u>. Continue this process for all attachments.

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| Attachment | Sav | Cancel |
| Document Type * | Select One | • |
| Attachment* | Browse No file selected. | |
| Document Name * | | |
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Answer all the questions related to Principal Investigator (PI) Obligations.



It is highly recommended to click on the <u>Check for Completeness</u> 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 <u>Save</u>.

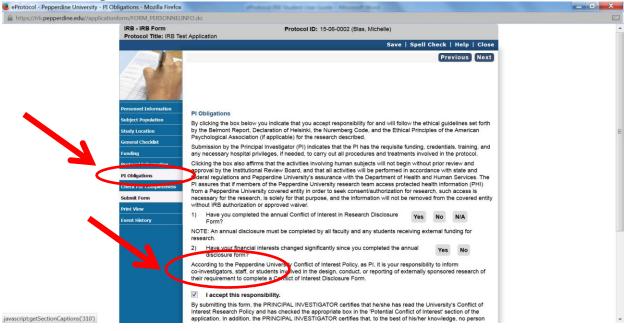
| | col ID: 15-06-0002 Principal Investigator: Blas, Michelle |
|--------|---|
| IRB Fo | |
| S.No. | Resolution |
| 1 | Risks - Complete Section 4. Specify N/A as appropriate. |
| 2 | Procedures to Maintain Confidentiality - Please select at least two safeguards for Electronic Data. |
| 3 | Procedures to Maintain Confidentiality - Please select at least two safeguards for Hardcopy Data. |
| 4 | Procedures to Maintain Confidentiality - Complete Sections 6(a) through 6(g). Specify N/A as appropriate. |
| 5 | Informed Consent - Complete Section 8. Specify N/A as appropriate. |
| - | Informed Consent - Add at least one Consent/Alteration of Consent/Waiver of Consent/Waiver of Written Consent/Addendui |
| 6 | in Section 8. |
| - | PI Obligations - Please review the content, answer the questions and check the checkboxes accepting responsibility and ab |
| 1 | obligations. |
| 8 | Subject Population - Complete Sections 3(i) through 3(I). Specify N/A as appropriate. |
| 9 | Benefits - Complete Section 5. Specify N/A as appropriate. |
| 10 | HIPAA - Complete Section 10. |

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." <u>Student Applications can only submitted after the Faculty</u> <u>Chair/Sponsor has approved the study</u>.

https://irb.pepperdin

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| The Faculty Chair/Sponsor has read and agrees to abide by the above obligations. | |
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After the **Faculty Chair/Sponsor** has approved the IRB application, submit the IRB application by clicking the <u>Submit Form</u> button. Be sure to check the box to agree to the PI obligations.



After selecting the <u>Submit Form</u>, you will be directed to this screen. Click <u>Yes</u>. 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.

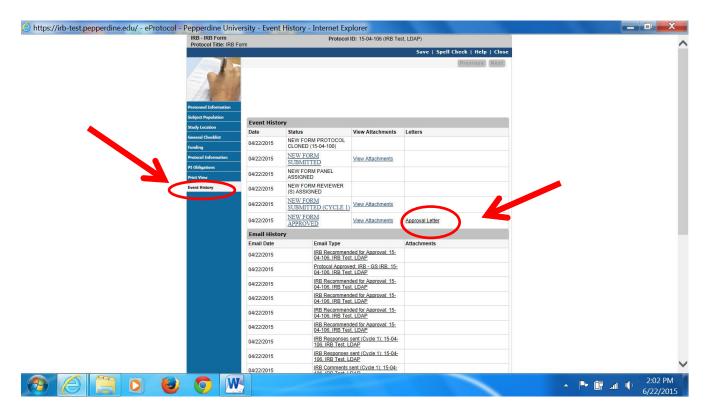
After submission, the IRB Office will review the IRB application for completeness. If there are any missing items or lacks content, the IRB application will be returned. If the application is completed, it will proceed to the IRB Committee for review. E-mails will be sent to the student for each major 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**.

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

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An e-mail notification will be sent when the IRB application has been approved. Login to the system at <u>https://irb.pepperdine.edu</u>. 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

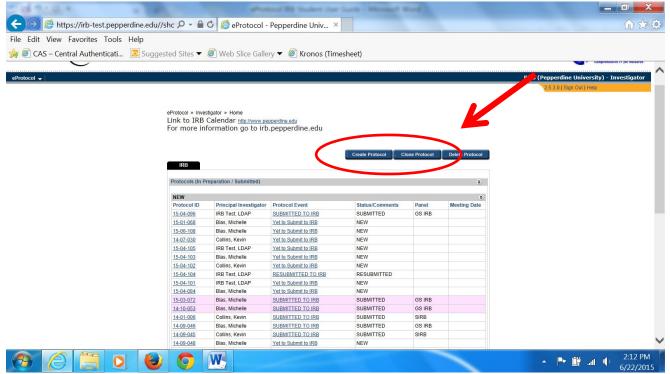
To make changes to an IRB application that has already been submitted, submit an amendment or modification and wait for IRB approval before implementing the change.

Continuing Review

Federal regulations require an IRB to conduct continuing reviews at least annually. A continuing review application should be submitted at least 1 - 2months 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, signon 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 <u>http://community.pepperdine.edu/irb/</u>.

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