

HOW TO:  
COMPLETE THE PERSONNEL CHANGES FORM



Study Number: **17-22211**  
 Study Alias: test  
 PI: Patel, Ami

## Submissions

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IRB Study Status: **Draft**    Study Number : 17-22211    IRB Study Title : test

Submissions    IRB Study Management

**Protocol Items**

- IRB Study Application
- Informed Consent ▶
- Other IRB Study Documents ▶

**IRB Submission Forms**

- Initial Review Submission Packet
- Continuing Review Submission Form
- Personnel Changes**
- Modification Form
- Study Closeout Report

**Post-Approval Event Reporting**

- Adverse Event Reporting Form
- Protocol Violation/Incident Report Form
- Reporting Form

**Add-On Study Application Forms**

**Outside Sites Forms**

- Outside Site Information

**GESCR**

- GESCR Subform

**Submissions History**

**IRB Study Communication**

**Outstanding Submission(s)**

Track Location	Ref Number	Request Type	Process Submission
There are no outstanding submissions.			

**Locate Personnel Form**

- ☛ Log onto iRIS.
- ☛ Locate the study.
- ☛ On study dashboard, locate and click on "Personnel Changes"



## Personnel Changes

### Instructions:

Use this form when the **ONLY** changes you are making are to Key Study Personnel (including PI).

**UCSF Key Study Personnel (KSP)** include the Principal Investigator, other investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved in using study participants' identifiable private information during the course of the research. Key Personnel also include faculty mentors/advisors who provide direct oversight to Postdoctoral Fellows, Residents and Clinical Fellows serving as PI on the IRB application.

Do **NOT** use this form when:

- You are making other modifications in addition to the Key Study Personnel changes. Instead, use the Modification Form.
- You are adding or removing personnel who do **not** meet the UCSF definition of Key Study Personnel. Instead, follow the IRB guidance for '**Research support staff or study contacts who are NOT Key Study Personnel.**'

There is **step-by-step guidance** on how to fill out this form on the **IRIS help site**.

### 1.2 Principal Investigator:

Ami Patel

### 1.3 Study Title:

test

### 1.4 Study Number:

- ☛ For **non-key study personnel**, refer to the instructions found here: [Research support staff or study contacts who are NOT Key Study Personnel](#)
- ☛ Do not fill out this form. 🚫

Number: **17-22212**  
 Alias: ABC

## Personnel Changes - (Version 1.0)

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Personnel Change Form

1.6 Submission Reference # (after the form is submitted, click the Refresh Constant Fields button to display the Reference #):

1.7 \* PERSONNEL CHANGES ONLY: Are you ONLY making changes to Key Study Personnel: (REQUIRED)

Yes  No

1.8 \* CONCURRENT CONTINUING REVIEW: Do you have a Continuing Review in process right now (e.g., the form has been submitted and you have not yet received your approval letter): (REQUIRED)

Yes  No

1.9 \* CONCURRENT MODIFICATIONS: Do you have another modification form or personnel change form under review by the UCSF IRB right now (e.g., the form has been submitted in iRIS and you have not yet received your approval letter): (REQUIRED)

Yes  No

\* Do you have any other types of changes (e.g. changes to personnel, funding, procedures, recruitment, consent forms, etc.) that need to be submitted to the IRB: (REQUIRED)

Yes  No

Are you ONLY making changes to Key Study Personnel?

Yes: You are adding or removing personnel who meets the definition of Key Study Personnel. Continue to next question.

No: Do not fill out this form. ❌

For non-key study personnel, refer to the instructions found here: [Research support staff or study contacts who are NOT Key Study Personnel](#)

Number: 17-22212

Alias: ABC

## Personnel Changes - (Version 1.0)

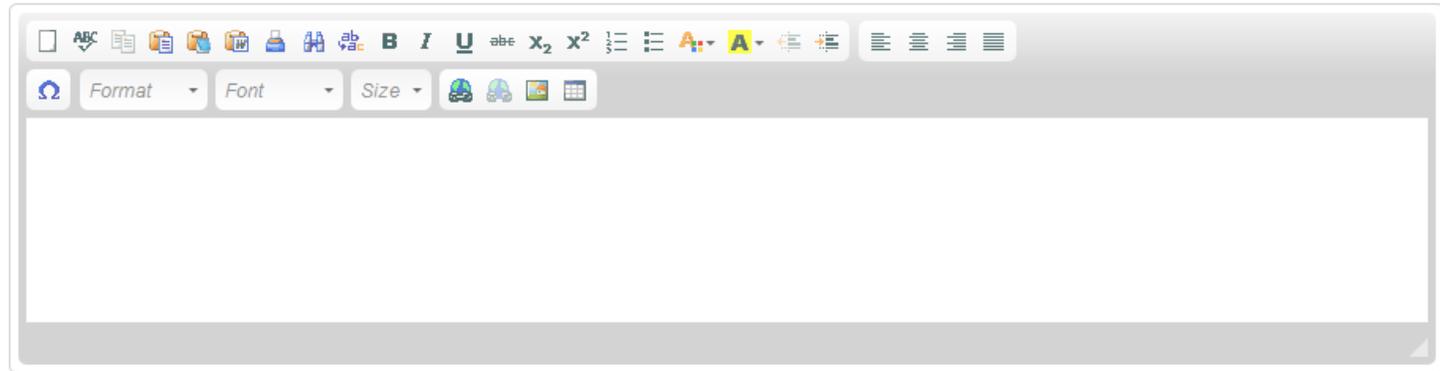
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Entire view of the Form

Personnel Change Form



1.6 Submission Reference # (after the form is submitted, click the Refresh Constant Fields button to display the Reference #):

1.7 \* PERSONNEL CHANGES ONLY: Are you ONLY making changes to Key Study Personnel: (REQUIRED)

Yes  No

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Yes  No

1.9 \* CONCURRENT MODIFICATIONS: Do you have another modification form or personnel change form under review by the UCSF IRB right now (e.g., the form has been submitted in iRIS and you have not yet received your approval letter): (REQUIRED)

Yes  No

\* Do you have any other types of changes (e.g. changes to personnel, funding, procedures, recruitment, consent forms, etc.) that need to be submitted to the IRB: (REQUIRED)

Yes  No

**Do you have a Continuing Review in process right now?**

**Yes:** Do **NOT** complete this Personnel Change form. ❌

Please wait to submit these changes until your Continuing Review has been approved. The IRB will not process modifications at the same time as annual renewals (i.e., 'continuing review') because it causes document and form version problems. Contact our office at [irb@ucsf.edu](mailto:irb@ucsf.edu) if you have questions about this policy.

**No:** Continue to next question.

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contractions and preparation for labor, while inflammatory markers can trigger prostaglandin production that may induce premature labor.<sup>7-10</sup> A small group of studies suggests that resilience to stress may protect against preterm birth and adverse pregnancy outcomes. For instance, positive affect, one of the most studied aspects of resilience, is associated with reduced risk of preterm delivery and increased length of gestation.<sup>9</sup> Positive affect has also been inversely associated with factors thought to mediate preterm delivery, including cortisol level, IL-6 and C-reactive protein concentrations in women.<sup>10</sup> Such studies drive our interest in the moderating effect of resilience.

1.6 Submission Reference # (after the form is submitted, click the Refresh Constant Fields button to display the Reference #):

1.7 \* PERSONNEL CHANGES ONLY: Are you ONLY making changes to Key Study Personnel: (REQUIRED)

Yes  No

1.8 \* CONCURRENT CONTINUING REVIEW: Do you have a Continuing Review in process right now (e.g., the form has been submitted and you have not yet received your approval letter): (REQUIRED)

Yes  No

1.9 \* CONCURRENT MODIFICATIONS: Do you have another modification form or personnel change form under review by the UCSF IRB right now (e.g., the form has been submitted in iRIS and you have not yet received your approval letter): (REQUIRED)

Yes  No

\* Do you have any other types of changes (e.g. changes to funding, procedures, recruitment, risks etc.) that need to be submitted to the IRB: (REQUIRED)

Yes  No

1.10 \* CHANGE OF PI: Is this modification being submitted to change the Principal Investigator (PI): (REQUIRED)

Yes  No

1.11 \* CHANGES TO FINANCIAL INTERESTS: Are there any changes in any financial interests related to this study or in any conflicts of interest of the PI or any other investigator?

Yes  No

1.12 \* REQUIRED TRAINING: Verification of Human Subjects Protection Training: (REQUIRED)

\* Have all new Key Study Personnel completed CITI Human Subjects Protection Training: (REQUIRED)

**Do you have another modification or change request form?**

**Yes:** Do NOT complete this Personnel Change form. ❌

Please wait to submit these changes until after you have received the approval letter for the modification in process. Processing more than one modification at the same time can cause document and form version problems.

**No:** Continue to next question.

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contractions and preparation for labor, while inflammatory markers can trigger prostaglandin production that may induce premature labor.<sup>7,8</sup> A small group of studies suggests that resilience to stress may protect against preterm birth and adverse pregnancy outcomes. For instance, positive affect, one of the most studied aspects of resilience, is associated with reduced risk of preterm delivery and increased length of gestation.<sup>9</sup> Positive affect has also been inversely associated with factors thought to mediate preterm delivery, including cortisol level, IL-6 and C-reactive protein concentrations in women.<sup>10</sup> Such studies drive our interest in the moderating effect of resilience.

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Yes  No

1.8 \* CONCURRENT CONTINUING REVIEW: Do you have a Continuing Review in process right now (e.g., the form has been submitted and you have not yet received your approval letter): (REQUIRED)

Yes  No

1.9 \* CONCURRENT MODIFICATIONS: Do you have another modification form or personnel change form under review by the UCSF IRB right now (e.g., the form has been submitted in iRIS and you have not yet received your approval letter): (REQUIRED)

Yes  No

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Yes  No

1.12 \* REQUIRED TRAINING: Verification of Human Subjects Protection Training: (REQUIRED)

\* Have all new Key Study Personnel completed CITI Human Subjects Protection Training: (REQUIRED)

**Do you have any other types of changes?**

**Yes:** Do NOT complete this Personnel Change form. ❌

Do not use the Personnel Change form as you indicated you are requesting approval to make other changes to the study. Please combine the other changes with these personnel changes into a single submission using the Modification form.

**No:** Continue to next question.



## Is this modification being submitted to change the Principal Investigator (PI)?

### Yes:

- Verify that the new PI's position corresponds with the selection under the follow-up question.
- Make sure to include documentation that the new PI will assume PI responsibilities for the study.
- Attach the following item in Section 1.14 below
  - IRB Application Form
- Attach the following item in Section 1.15 below
  - A letter signed by the outgoing PI requesting the change
  - Revised consent forms and other participant-contact documents that name the PI

**No:** Continue to next question.

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has been submitted in iRIS and you have not yet received your approval letter): (REQUIRED)

Yes  No

\* Do you have any other types of changes (e.g. changes to funding, procedures, recruitment, risks etc.) that need to be submitted to the IRB: (REQUIRED)

Yes  No

1.10 \* CHANGE OF PI: Is this modification being submitted to change the Principal Investigator (PI): (REQUIRED)

Yes  No

1.11 \* CHANGES TO FINANCIAL INTERESTS: Are there any changes in any financial interests related to this study or in any conflicts of interest of the PI or any other investigator?

Yes  No

1.12 \* REQUIRED TRAINING: Verification of Human Subjects Protection Training: (REQUIRED)

\* Have all new Key Study Personnel completed CITI Human Subjects Protection Training: (REQUIRED)

Yes  No

1.13 \* DESCRIPTION OF CHANGES: Describe the personnel changes that are being made: (REQUIRED)

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## Have all the new key study personnel completed the required Human Subjects Protection Training?

**Yes:** To verify all Key Study Personnel has completed CITI Human Subjects Protection Training for study approval, check the following lists: [UCSF CITI Completion list](#) and the [SFVAMC list](#).

**No:** If the PI lacks current CITI Human Subjects Protection Training, your submission can be reviewed, but **CANNOT** be approved until the PI completes or renews the CITI training. Please complete the training for study approval.

All Key Study Personnel, including non-PI KSP, must complete [CITI Human Subjects Protection Training](#) before participating in any study activities.

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has been submitted in iRIS and you have not yet received your approval letter): (REQUIRED)

Yes  No

\* Do you have any other types of changes (e.g. changes to funding, procedures, recruitment, risks etc.) that need to be submitted to the IRB: (REQUIRED)

Yes  No

1.10 \* CHANGE OF PI: Is this modification being submitted to change the Principal Investigator (PI): (REQUIRED)

Yes  No

1.11 \* CHANGES TO FINANCIAL INTERESTS: Are there any changes in any financial interests related to this study or in any conflicts of interest of the PI or any other investigator?

Yes  No

1.12 \* REQUIRED TRAINING: Verification of Human Subjects Protection Training: (REQUIRED)

\* Have all new Key Study Personnel completed CITI Human Subjects Protection Training: (REQUIRED)

Yes  No

1.13 \* DESCRIPTION OF CHANGES: Describe the personnel changes that are being made: (REQUIRED)

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be submitted to the IRB: **(REQUIRED)**  
 Yes  No

**1.10 \* CHANGE OF PI: Is this modification being submitted to change the Principal Investigator (PI): (REQUIRED)**  
 Yes  No

**1.11 \* CHANGES TO FINANCIAL INTERESTS: Are there any changes in any financial interests related to this study or in any conflicts of interest of the PI or any other investigator?**  
 Yes  No

**1.12 \* REQUIRED TRAINING: Verification of Human Subjects Protection Training: (REQUIRED)**  
  
\* Have all new Key Study Personnel completed **CITI Human Subjects Protection Training: (REQUIRED)**  
 Yes  No

**1.13 \* DESCRIPTION OF CHANGES: Describe the personnel changes that are being made: (REQUIRED)**

Rich text editor toolbar with icons for undo, redo, bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, and a text area below.

**Description of Changes: Describe the personnel changes that are being made:**

Note: Use this section to include an itemized list of all personnel changes being requested as part of this personnel change request.

Study Number: **16-18799**  
Study Alias: Stress during Pregnancy  
PI: Weiss, Sandra J, RN, PhD, FAAN

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1.0 Personnel Change Form

### 1.14 \* REVISED STUDY APPLICATION: (REQUIRED)

Please update the 'Grant Key Study Personnel Access to the Study' and 'Qualifications of Key Study Personnel' sections of the application to reflect the changes in personnel.

 Click here to attach the application.

No Application has been associated with this submission.

### 1.15 REVISED DOCUMENTS AND CONSENT FORMS:

\* Do you need to attach any revised consent forms: (REQUIRED)

Yes  No

\* Do you need to attach any new or revised Study Documents: (REQUIRED)

Yes  No

### 1.16 ADDITIONAL INFORMATION: Are there any special processing requests or some additional information you would like to provide:

Note: The IRB tries to accommodate special requests but it's not always possible. Thank you for your cooperation!



## Revised Study Application (Required):

Click the gray bar to revise and attach your Study Application.

Study Number: **16-18799**  
 Study Alias: Stress during Pregnancy  
 PI: Weiss, Sandra J, RN, PhD, FAAN

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**1.14 \* REVISED STUDY APPLICATION: (REQUIRED)**

Please update the 'Grant Key Study Personnel Access to the Study' and 'Qualifications of Key Study Personnel' sections of the application to reflect the changes in personnel.

[Click here to attach the application.](#)

No Application has been associated with this submission.

**1.15 REVISED DOCUMENTS AND CONSENT FORMS:**

\* Do you need to attach any revised consent forms: **(REQUIRED)**

Yes  No

\* Do you need to attach any new or revised Study Documents: **(REQUIRED)**

Yes  No

**1.16 ADDITIONAL INFORMATION: Are there any special processing requests or some additional information you would like to provide:**

Note: The IRB tries to accommodate special requests but it's not always possible. Thank you for your cooperation!

**New and/or revised documents and consent forms:**

**Yes:** If your request involves PI change, this should be 'yes'. Attach revised consent document(s).

**No:** Select "No" if your request involves personnel changes that do not require changes to the consent documents.

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### 1.15 REVISED DOCUMENTS AND CONSENT FORMS:

\* Do you need to attach any revised consent forms: **(REQUIRED)**

Yes  No

Click the 'Select or Revise Existing' button to attach revised consent forms.

If you don't need to attach any consent forms, change your answer to 'No' above to skip attaching consent forms.

 **Select or Revise Existing**  **Add a New Consent**

Detach	Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	View Document
No Consent(s) have been attached to this form.								

\* Do you need to attach any new or revised Study Documents: **(REQUIRED)**

Yes  No

\* Type(s) of study documents: **(REQUIRED)**

New study document (i.e., letter of support for change of PI, CITI training certificates, PI eligibility form, etc.)

Revised study document (previous version has already been submitted to the UCSF IRB)

If you don't need to attach any study documents, change your answer to 'No' above to skip attaching documents.

 **Select or Revise Existing**  **Add a New Document**  **Add Multiple Documents**

Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	View Document
No Document(s) have been attached to this form.							

Attach revised consent forms (only appears if the answer to the preceding question is "yes")

☛ If you indicated "Yes" to the previous question, click "Select or Revise Existing" to attach the revised consent form.

Study Number: **16-18799**  
Study Alias: Stress during Pregnancy  
PI: Weiss, Sandra J, RN, PhD, FAAN

## Personnel Changes - (Version 1.0)

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### 1.14 \* REVISED STUDY APPLICATION: (REQUIRED)

Please update the 'Grant Key Study Personnel Access to the Study' and 'Qualifications of Key Study Personnel' sections of the application to reflect the changes in personnel.

 [Click here to attach the application.](#)

No Application has been associated with this submission.

### 1.15 REVISED DOCUMENTS AND CONSENT FORMS:

\* Do you need to attach any revised consent forms: (REQUIRED)

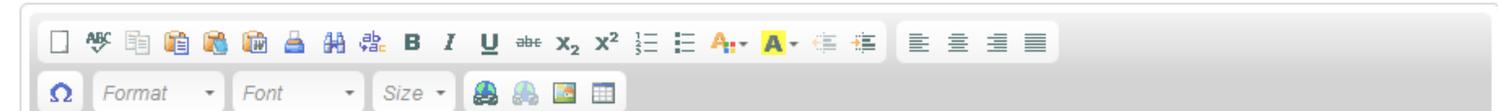
Yes  No

\* Do you need to attach any new or revised Study Documents: (REQUIRED)

Yes  No

### 1.16 ADDITIONAL INFORMATION: Are there any special processing requests or some additional information you would like to provide:

Note: The IRB tries to accommodate special requests but it's not always possible. Thank you for your cooperation!

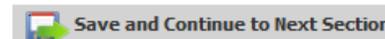
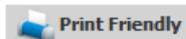


**Do you need to attach any new or revised Study Documents?**

**Yes:** Attach any *revised or new* study materials listing the PI or other study personnel.

**No:** Some personnel change requests may involve only people who are not listed on recruitment documents or other study materials.

Check *current approved* recruitment documents and make sure the PI or other personnel are listed.



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### 1.15 REVISED DOCUMENTS AND CONSENT FORMS:

\* Do you need to attach any revised consent forms: **(REQUIRED)**

Yes  No

Click the 'Select or Revise Existing' button to attach revised consent forms.

If you don't need to attach any consent forms, change your answer to 'No' above to skip attaching consent forms.

Select or Revise Existing

Add a New Consent

Detach	Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	View Document
No Consent(s) have been attached to this form.								

\* Do you need to attach any new or revised Study Documents: **(REQUIRED)**

Yes  No

\* Type(s) of study documents: **(REQUIRED)**

New study document (i.e., letter of support for change of PI, CITI training certificates, PI eligibility form, etc.)

Revised study document (previous version has already been submitted to the UCSF IRB)

If you don't need to attach any study documents, change your answer to 'No' above to skip attaching documents.

Select or Revise Existing

Add a New Document

Add Multiple Documents

Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	View Document
No Document(s) have been attached to this form.							

☛ If you indicated "Yes" to the previous question, indicate if you are submitting new and/or revised documents.

#### Type(s) of study documents:

☛ If you indicated "Yes" to the previous question, attach any revised or new study documents.

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VERSION	Date	DOCUMENT
No Document(s) have been attached to this form.		

**Submission Tip:**

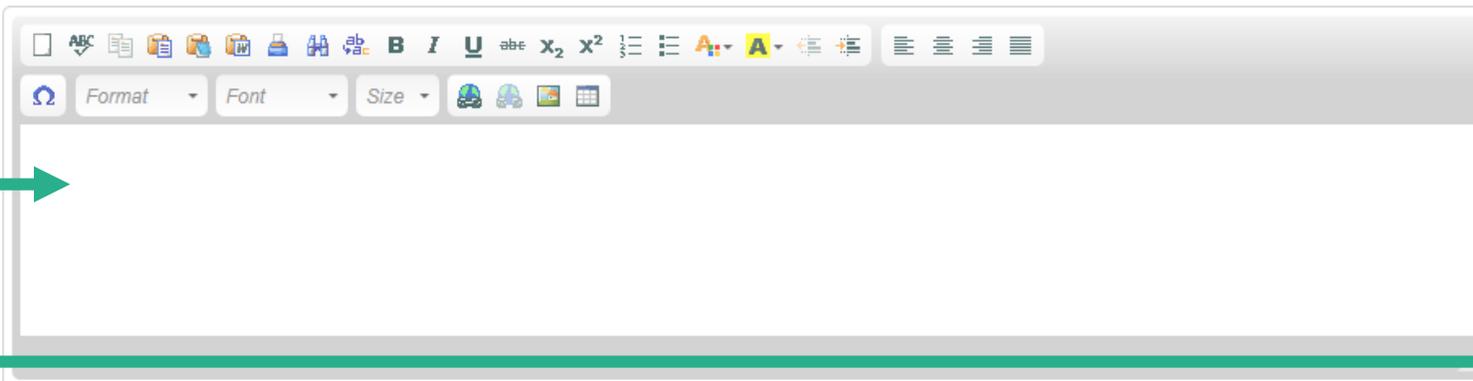
If you are submitting updated versions of consent forms or documents that have previously been submitted and approved by the UCSF IRB, please:

- ensure they have been uploaded as revisions to the approved versions
- use the compare documents function to ensure that all of the changes in the documents match what is described in this form

Your submission will be returned if additional changes are included. Uploading 'revised documents' as 'new' documents may delay approval.

**1.16 ADDITIONAL INFORMATION: Are there any special processing requests or some additional information you would like to provide:**

Note: The IRB tries to accommodate special requests but it's not always possible. Thank you for your cooperation!



**1.17**

**END OF FORM**

Click 'Save and Continue to the Next Section' to get to the 'Signoff and Submit' screen.

Are there any special processing requests or some additional information you would like to provide?

- While not all requests can be accommodated, please let us know if there is any special processing requests for this particular form.
- Click "Save and Continue to the Next Section" when you are done with this form.