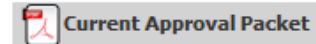


HOW TO:

COMPLETE THE 'PROTOCOL ENROLLMENT EXCEPTION REQUEST' FORM

UPDATED 1/9/2018





## Protocol Items

## Protocol Items

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

## IRB Submission Forms

## IRB Submission Forms

- Initial Review Submission Packet
- Continuing Review Submission
- Personnel Changes
- Modification Form
- Protocol Enrollment Exception Request Form
- Study Closeout Report

## Post-Approval Event Reporting

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

- Submissions History
- IRB Study Communication

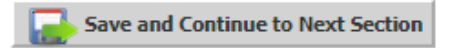
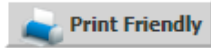


## Outstanding Submission(s)

Track Location	Ref Number	Request Type
	189435	Click on the hyperlink to edit/view Study Closeout Report

## Locate Protocol Enrollment Exception Form

- ☛ Log onto iRIS.
- ☛ Locate the study.
- ☛ On study dashboard, locate and click on "Protocol Enrollment Exception Request Form"



Entire view of the Form

## 1.0 Protocol Enrollment Exception Request Form

### Instructions:

Use this form only when you are requesting a **planned, one-time enrollment of a person who does not meet eligibility criteria for inclusion** (see our [guidance](#)). Protocol enrollment exception requests must be approved by the UCSF IRB prior to the person being enrolled.

### 1.2 Principal Investigator:

Sandra J Weiss, RN, PhD, FAAN

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

### 1.4 Study Title:

Effects of Stress and Depression on Biomarkers associated with Preterm Birth (transferred from test system study 15-13391)

### 1.5 Study Number:

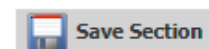
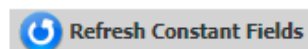
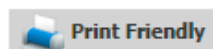
16-18799

### 1.6 Lay Summary:

Review the [guidance](#) for protocol enrollment exceptions to make sure you are using the right form.

**Important!** If you are making a permanent change to the protocol, do not fill out this form. Instead, fill out a Modification Form.

## Protocol Enrollment Exception Request Form - (Version 1.0)



Entire view of the Form

Enrollment Exception Status: Has the individual you are requesting this exception for already been enrolled?

Yes: **Do not fill out this form** ❌

Instead, submit a Protocol Violation/Incident Report form.

1.7 \* ENROLLMENT EXCEPTION STATUS: Has the individual you are requesting this exception for already been enrolled: (REQUIRED)

Yes  No

1.8 \* ADDITIONAL CHANGES: Do you have changes other than the Enrollment Exception that you would like to make to your study at this

Yes  No

1.9 \* VA STUDIES: Are you requesting to enroll a VA patient? (REQUIRED)

Yes  No

1.10 \* DESCRIPTION: Protocol enrollment exception request description: (REQUIRED)

\*Describe the protocol enrollment exception request you are making and provide the rationale for this request. **You must provide the specific inclusion/exclusion criteria that excludes the person from being enrolled per protocol:** (REQUIRED)



## Protocol Enrollment Exception Request Form - (Version 1.0)

 Print Friendly  Refresh Constant Fields  Save Section  Save and Continue to Next Section

Entire view of the Form

1.7 \* ENROLLMENT EXCEPTION STATUS: Has the individual you are requesting this exception for already been enrolled: (REQUIRED)

Yes  No

1.8 \* ADDITIONAL CHANGES: Do you have changes other than the Enrollment Exception that you would like to make to your study at this time: (REQUIRED)

Yes  No

1.9 \* VA STUDIES: Are you requesting to enroll a VA patient? (REQUIRED)

Yes  No

1.10 \* DESCRIPTION: Protocol enrollment exception request description: (REQUIRED)

\*Describe the protocol enrollment exception request you are making and provide the rationale for this request. **You must cite the specific inclusion/exclusion criteria that excludes the person from being enrolled per protocol: (REQUIRED)**

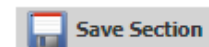
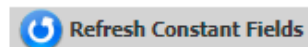
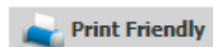
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**Additional Changes: Do you have changes other than the Enrollment Exception that you would like to make to your study at this time?**

**Yes:** Only use this form for Enrollment Exception requests. All other changes should be submitted using the Modification Form or the Personnel Changes Form, as appropriate.

**Note:** Wait until the Enrollment Exception request has been reviewed by the IRB before submitting the other changes.

## Protocol Enrollment Exception Request Form - (Version 1.0)



Entire view of the Form

1.7 \* ENROLLMENT EXCEPTION STATUS: Has the individual you are requesting this exception for already been enrolled: (REQUIRED)

Yes  No

1.8 \* ADDITIONAL CHANGES: Do you have changes other than the Enrollment Exception that you would like to make to your study at this

Yes  No

1.9 \* VA STUDIES: Are you requesting to enroll a VA patient? (REQUIRED)

Yes  No

1.10 \* DESCRIPTION: Protocol enrollment exception request description: (REQUIRED)

\*Describe the protocol enrollment exception request you are making and provide the rationale for this request. **You must provide the specific inclusion/exclusion criteria that excludes the person from being enrolled per protocol:** (REQUIRED)



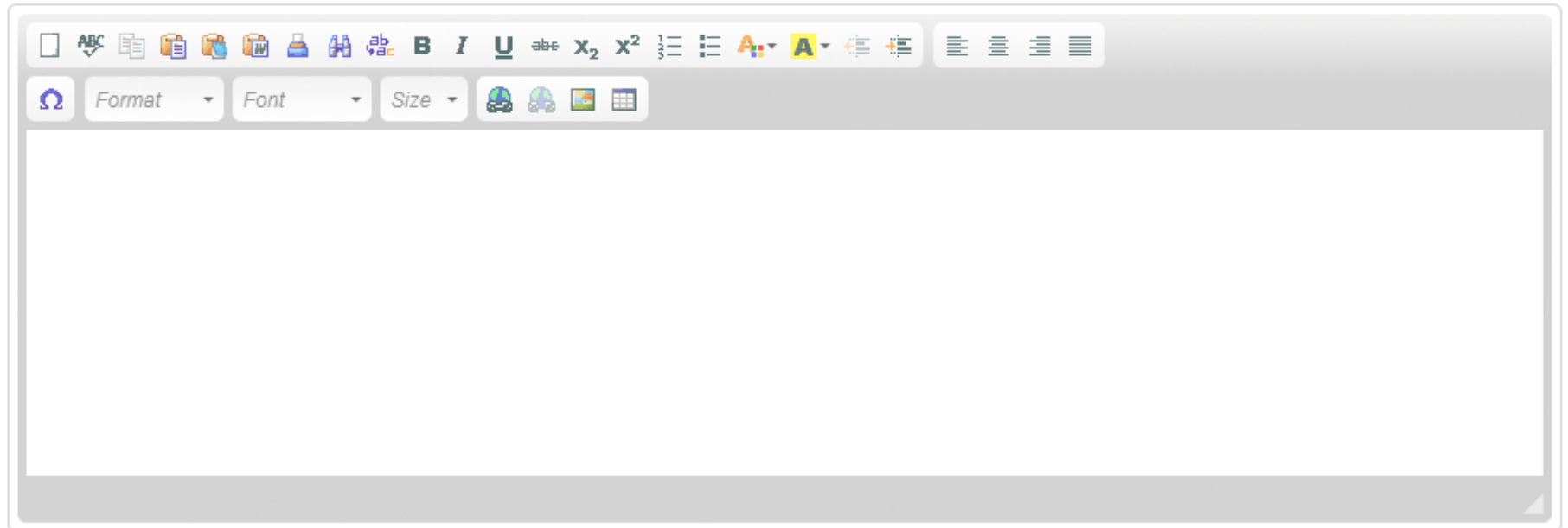
**VA Studies: Are you requesting to enroll a VA patient?**

**Note:** This question will only appear if the VA is listed as a site in your approved IRB application.

Entire view of the Form

1.10 \* DESCRIPTION: Protocol enrollment exception request description: (REQUIRED)

\*Describe the protocol enrollment exception request you are making and provide the rationale for this request. **You must cite the specific inclusion/exclusion criteria that excludes the person from being enrolled per protocol: (REQUIRED)**



\* For the potential participant, does enrollment in this study pose new risks not currently listed in the approved consent form or increase the likelihood or severity of experiencing the known risks: (REQUIRED)

Yes  No

**Yes:** If yes, do the following:

1. Describe the risks in the following question on the form.
2. Attach an **addendum consent form** detailing the risks. For guidance, refer to the Addendum Consent Template on the IRB website.

**Description:** Explain how to participant will benefit from this enrollment exception. Also include any additional risk not already mentioned in the approved informed consent.

**Is this a sponsored study:**

**Yes:** Attach a copy of the sponsor's approval memo in the last question of this form.

**No:** By submitting this protocol exception request, you are providing assurance that the Principal Investigator has reviewed and approved the proposed exception.

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Entire view of the Form

\*Explain how this protocol enrollment exception might benefit the person. List any additional risks that might affect this person that are not described in the currently approved informed consent form: **(REQUIRED)**

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\*Is this a sponsored study: **(REQUIRED)**

Yes  No



Entire view of the Form

**1.11 \* IMPACT ANALYSIS:** With respect to the generalizability of the data, please comment on the impact this protocol enrollment exception may have on the analyses and whether or not there would be a compromise of generalizability of results. The IRB recommends limiting exceptions as much as possible to avoid compromising the generalizability of your study results: **(REQUIRED)**



A rich text editor toolbar with various icons for text formatting and insertion. The icons include undo, redo, bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, insert link, insert image, insert table, and insert video. Below the toolbar are three dropdown menus labeled 'Format', 'Font', and 'Size', followed by icons for link, unlink, insert link, and insert image.

**Impact Analysis:**  
Describe impact on future analyses if this enrollment exception is approved.

**1.12 \* LOCAL EXCEPTION HISTORY:** Have there been any previous requests for protocol enrollment exceptions on this study at UCSF or at one of its affiliated sites: **(REQUIRED)**

Yes  No

## Local Exception History

Yes:

Enter the number of exceptions previously requested.

Comment whether other exceptions were related to the same enrollment criteria.

**Note:** For an extensive list of all UCSF affiliated sites, click here:  
<https://irb.ucsf.edu/ucsf-affiliated-institutions>

1.12 \* LOCAL EXCEPTION HISTORY: Have there been any previous requests for protocol enrollment exceptions on this study at UCSF or at one of its affiliated sites: **(REQUIRED)**

Yes  No

\* How many exceptions have been requested under this approval: **(REQUIRED)**

\* Please briefly comment whether the other exceptions were related to the same enrollment criteria. If so, please explain why the enrollment criteria are not being broadened at this time: **(REQUIRED)**

Rich text editor toolbar with icons for text formatting (bold, italic, underline, strikethrough, subscript, superscript, bulleted list, numbered list), text color, background color, link, unlink, and table insertion.

Dropdown menus for Format, Font, and Size.

Rich text editor content area.

### New Documents and Consent

**Yes:** If yes, upload your new consent as a *Word Document*.

### New Documents and Consent Forms:

**Yes:** Attach new documents (i.e. Sponsor's approval) here.

**No:** If no, make sure your form is complete and press **save and continue**.

#### 1.13 NEW DOCUMENTS AND CONSENT FORMS:

\* Do you need to attach a consent addendum or new consent form (e.g., you want to enroll a minor and need to add parental consent and assent forms): **(REQUIRED)**

Yes  No

**Upload consent forms as Word documents rather than PDFs.**

\* Do you need to attach any new Study Documents, (e.g., Sponsor's approval memo): **(REQUIRED)**

Yes  No

**Click 'Add a New Document' or 'Add Multiple Documents' to add brand new documents that have never been submitted before.**

1.14

## END OF FORM

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