HOW TO:

COMPLETE THE ‘PROTOCOL ENROLLMENT EXCEPTION REQUEST’ FORM

UPDATED 1/9/2018
Log onto iRIS.
Locate the study.
On study dashboard, locate and click on “Protocol Enrollment Exception Request Form”
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.

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 RefreshConstant 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:
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.
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.
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.

<table>
<thead>
<tr>
<th>1.7</th>
<th>ENROLLMENT EXCEPTION STATUS: Has the individual you are requesting this exception for already been enrolled? (REQUIRED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔</td>
<td>Yes □ No □</td>
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<tr>
<th>1.8</th>
<th>ADDITIONAL CHANGES: Do you have changes other than the Enrollment Exception that you would like to make to your study at this time?</th>
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<tbody>
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<td>✔</td>
<td>Yes □ No □</td>
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<tr>
<th>1.9</th>
<th>VA STUDIES: Are you requesting to enroll a VA patient? (REQUIRED)</th>
</tr>
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<tbody>
<tr>
<td>✔</td>
<td>Yes □ No □</td>
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<tr>
<th>1.10</th>
<th>DESCRIPTION: Protocol enrollment exception request description: (REQUIRED)</th>
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<tbody>
<tr>
<td></td>
<td>✗ Describe the protocol enrollment exception request you are making and provide the rationale for this request. You must include the specific inclusion/exclusion criteria that excludes the person from being enrolled per protocol. (REQUIRED)</td>
</tr>
</tbody>
</table>
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.

* 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)
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.

Description: Explain how the participant will benefit from this enrollment exception. Additionally, include any additional risk not already mentioned in the approved informed consent.
Impact Analysis:
Describe impact on future analyses if this enrollment exception is approved.
**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

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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)**
Protocol Enrollment Exception Request Form

**New Documents and Consent**

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

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

**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.*

**END OF FORM**

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