

Site Close Out Notification Form

Total IRB does not consider a site closed until the following have occurred:

- All subjects at the site have completed all visits including any follow up period required by the protocol (via phone call, visit, letter, etc.).
- All data has been collected.

Do not submit this form until all of the above is complete.

I. STUDY INFORMATION	
Principal Investigator:	
Protocol Number:	
Sponsor name and/or Funding Agency:	

II. SITE CLOSURE INFORMATION	
1. Did your site ever initiate study activity?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Are all study activities now complete?	<input type="checkbox"/> Yes <input type="checkbox"/> No*
<p>* If No, site cannot be closed. Wait until all activities are complete to submit close out notification form. If activities are not complete and IRB approval is expiring, complete <i>Continuing Review Form</i> and submit to Total IRB.</p>	

III. ENROLLMENT INFORMATION	
1. Were subjects screened at your site?	<input type="checkbox"/> Yes <input type="checkbox"/> No*
<p>* If No, skip to section V of this form</p>	
2. Number of subjects who signed an informed consent form during study:	

III. ENROLLMENT INFORMATION	
3. Number of screen failures:	
4. Number of subjects who entered into the study (i.e. randomized for randomized trials):	
5. Of the patients who entered the study, indicate the totals below:	
Completed:	Lost to Follow Up:
Withdrew Consent:	Withdrew due to AE:
Discontinued by Sponsor:	Other*:
* Indicate reasons for subject withdrawal or early termination for all subjects included in "other" category above:	
6. Were advertising materials used for this study? <input type="checkbox"/> Yes* <input type="checkbox"/> No	
7. If yes to item 6 above, were the advertising materials approved by Total IRB prior to use? <input type="checkbox"/> Yes <input type="checkbox"/> No* * If No, attach a copy of the materials and letter of explanation.	

IV. SUBJECT DIVERSITY
Gender: Percent (%) of subjects that signed informed consent form (ICF) that were male : _____ % Percent (%) of subjects that signed ICF that were female : _____ % <div style="text-align: right;"><i>Note: should total to 100%</i></div>
Ethnicity: Percent (%) of subjects that signed ICF that were Hispanic or Latino: _____ % Percent (%) of subjects that signed ICF that were Not Hispanic or Latino: _____ % <div style="text-align: right;"><i>Note: should total to 100%</i></div>

Race:

- Percent (%) of subjects that signed ICF that were African-American: _____ %
 Percent (%) of subjects that signed ICF that were American Indian: _____ %
 Percent (%) of subjects that signed ICF form that were Asian: _____ %
 Percent (%) of subjects that signed ICF that were Caucasian: _____ %
 Percent (%) of subjects that signed ICF that were Other Race: _____ %

Note: should total to 100%

V. SAFETY

<p>1. Were there any issues regarding risks to subjects or others at your site that have not already been reported to Total IRB? * If Yes, complete appropriate reporting form (e.g. SAE/ADE Notification Form, Protocol Deviation Report Form, etc.) along with this report.</p>	<p><input type="checkbox"/> Yes* <input type="checkbox"/> No</p>
<p>2. Have any participants at your site requested compensation for an injury associated with the study that has not been previously reported to Total IRB? * If Yes, attach a letter of explanation.</p>	<p><input type="checkbox"/> Yes* <input type="checkbox"/> No</p>
<p>3. Is there any new information that could influence Total IRB's assessment of risk or benefit to subjects? *If Yes, attach a letter of explanation.</p>	<p><input type="checkbox"/> Yes* <input type="checkbox"/> No</p>
<p>4. Was the informed consent presented to all subjects in an appropriate manner? *If No, attach a letter of explanation.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No*</p>
<p>5. Did the PI personally conduct and/or supervise this study? *If No, attach a letter of explanation.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No*</p>

VI. PERSON COMPLETING FORM

By submitting this form I certify that the information contained is complete and accurate and that no facts have

By submitting this form I certify that the information contained is complete and accurate and that no facts have been suppressed or misstated. The Principal Investigator (PI) is aware of all information in this form and I am authorized to submit to the IRB on the PI's behalf.

Form Completed By

Date

Title, Company