

Principal Investigator Site Closeout Report



DO NOT submit this form unless you intend for your site to be closed with Copernicus Group IRB

This form may be submitted by fax (919-465-4311) or scanned and e-mailed (irb@cgirb.com).

Blank & Incomplete Answers Will Result in Delayed Reviews!

- Please complete this Principal Investigator Site Closeout Report if your study is closed or otherwise terminated and submit to CGIRB for review. Upon closure, acknowledgement will be sent.
 - Do **not** use this form for principal investigator (PI) transfers. Complete the **Principal Investigator Transfer Form**, located on the CGIRB website (<http://www.cgirb.com>).
- If you have additional sites participating in this CGIRB-approved study, you should not submit this form until all of the sites have completed all study-related activities.
- Note: CGIRB processes all events that are reportable under CGIRB's unanticipated problems policy for up to 6 months after study/site closure.
- Refer to the **CGIRB Investigator Guidebook** for additional information about study closure at a PI site.

Protocol #:	IRB Tracking #:
Principal Investigator (PI):	
Site/Center Name:	
PI Phone #	PI Fax #
PI E-mail:	

SECTION 1:

This research study is: **Please select one:**

<input type="checkbox"/>	Closed	NO subjects were screened or enrolled. Complete and date section 3 and submit. (Do NOT complete section 2.)
<input type="checkbox"/>	Closed	Subjects were enrolled and have completed all applicable study visits; No Active subjects remain in the study (including subjects being followed for any reason, e.g. safety follow-up) Complete sections 2 and 3.
<input type="checkbox"/>	Closed	Other (specify) _____ Complete sections 2 and 3. Attach additional documentation as necessary.

If enrollment is closed but you expect subjects to remain active in the study (eg, completing remaining study visits) you MAY NOT close your site.

SECTION 2:

Since the **START** of the study or most recent continuing review:

YES NO

2A.	Have any unanticipated problems involving risks to research subjects or others occurred at your site that have not previously been reported to CGIRB?	<input type="checkbox"/>	<input type="checkbox"/>
NOTE: To determine which events are reportable under CGIRB's unanticipated problems policy and how to submit them, refer to the CGIRB Investigator Guidebook .			
If <u>YES</u>, attach documentation to this report			

For questions, you may contact CGIRB at (888) 303-2224. For the best service, have your IRB tracking number ready!

YES NO

Since the **START** of the study or most recent continuing review:

2B.	Have any changes/modifications to the research taken place that have not yet been reported to CGIRB (including changes made without prior IRB approval in order to avoid an apparent, immediate hazard to human subjects)? If <u>YES</u> ensure these are submitted as attachments to this report.	<input type="checkbox"/>	<input type="checkbox"/>
2C.	Has there been any complaint by a subject or other, where the complaint indicates an unexpected risk or cannot be resolved by the research staff, which has not been previously reported to CGIRB? If <u>YES</u> attach an explanation	<input type="checkbox"/>	<input type="checkbox"/>
2D.	Has any subject sought compensation for injury associated with this study at your site? If <u>YES</u> attach an explanation	<input type="checkbox"/>	<input type="checkbox"/>
2E.	Has the Food and Drug Administration (FDA), or Office of Human Research Protection (OHRP), or other regulatory agency inspected/evaluated your site since the start of the study or the most recent continuing review? If 2E is checked <u>YES</u> : was a Form FDA 483 or list of objectionable observations issued? If <u>YES</u>, attach the observations and your response letter	<input type="checkbox"/>	<input type="checkbox"/>
2F.	Has your state medical license been revoked, sanctioned, or suspended? If <u>YES</u>, attach an explanation	<input type="checkbox"/>	<input type="checkbox"/>
2G.	Are there any new findings or relevant information that may affect the risk/benefit ratio of this study? If <u>YES</u>, attach an explanation	<input type="checkbox"/>	<input type="checkbox"/>

SECTION 3:

<p>By submitting this form, I am confirming that I am the Principal Investigator (PI) or the PI's designee authorized to submit on behalf of the PI. The information within this form is accurate and complete with the PI's full awareness of the information submitted.</p>

Submitter's e-mail address

Name of Individual at Site Completing Form

Title of Individual at Site Completing Form

Date

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