



## *CLOSE-OUT FORM (3D/V1/2015)*

*To the Principal Investigator:*

*Please be advised that upon study completion or site closure, a Close-out Report must be submitted for review and approval. IEC retention period of study files is three (3) years following study closure.*

*Please obtain an electronic copy of this Form, fill-out the requested information, and make your submission both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.*

<b>I. PROTOCOL INFORMATION</b>	<b>IEC Protocol Tracking No.</b>
Study Protocol No.	Protocol Approval Date: <dd/mm/yy>
Study Initiation Date: <dd/mm/yy>	Expected End Date: <dd/mm/yy>
Title:	Version Number, Date
Name of Principal Investigator	Contact Nos.:
Sponsor/CRO	
Study Site	
Type of Review ( <i>To be determined by IEC</i> ) <input type="checkbox"/> Full Board <input type="checkbox"/> Expedited	

<b>II. INFORMATION REQUIRED</b>	<b>Close-Out REPORT SUBMISSION DATE</b> <dd/mm/yy>
	<b><i>Response/ Comments</i></b>
1. Continuing Review Application submission date and IEC recommendation	
2. Protocol Amendments, if any, and date(s) of approval	
3. Study Objectives	
4. Duration of the study	
5. Number of study arms	
6. Total number of participants approved for recruitment	
7. Total number of participants recruited	
8. Number of patients withdrawn, if any, and reason(s) for their	



withdrawal	
9. Number and nature of protocol deviations/violations, if any	
10. Were all SAEs reported to IEC? <input type="checkbox"/> Yes <input type="checkbox"/> NO ( <i>provide a summary describing the number and nature of the unreported SAEs</i> )	
11. Summary of participant's queries, complaints/grievances, if any, regarding conduct of the study	
12. Difficulties encountered during the study, if any	
<p><i>I declare that the above information/statements are true and correct to the best of my knowledge.</i></p> <p>_____</p> <p><i>Signature Over Printed Name of Principal Investigator</i> <span style="float: right;">_____</span> <i>Date:</i></p>	

III. IEC RECOMMENDATION	Specifics
<input type="checkbox"/> NO FURTHER ACTION REQUIRED <input type="checkbox"/> REQUEST INFORMATION <input type="checkbox"/> RECOMMENDED FURTHER ACTION	
Reviewer <input type="checkbox"/> Primary <input type="checkbox"/> Secondary	<p>_____</p> <p><i>Reviewer's Signature Over Printed Name</i> <span style="float: right;">_____</span> <i>Date</i></p>