Print form

VERITAS IRB

SPONSOR REVIEW OF ONGOING RESEARCH REPORT

1. ADMINISTRATIVE INFORMATION

Name of Submitting Party:			
Company Name:			
Phone	( ) -	Fax	( ) -
Email Address:			
Street			
City:		Province / State:	
Country:		Postal / Zip Code:	

2. STUDY IDENTIFICATION

Sponsor of the Research:		
Protocol Number:		(If there is no Protocol Number check here: ☐)
Protocol Title:		

3. STUDY ENROLMENT

☐ Study not yet initiated:
- ☐ Funding issues
- ☐ Other: _____

☐ Study is dormant:
- ☐ Funding issues
- ☐ Accrual problems (see recruitment difficulties below)
- ☐ Other: _____

☐ Enrolment open and is at: _____ percent of projected enrolment.

☐ Enrolment closed – experimental procedures continue.
Date last Participant enrolled: _____/_____/_____
DD MM YYYY

☐ Enrolment closed – follow-up only. No further experimental procedures.
Date last Participant enrolled: _____/_____/_____
DD MM YYYY

Projected Study Closure Date: _____/_____/_____
DD MM YYYY

Number of Study Sites participating in Study under the jurisdiction of the Veritas IRB:	
Number of Study Sites under the jurisdiction of the Veritas IRB withdrawn from Study: (do not include screen failures)	
If any, please provide reasons for Site withdrawal:	
Total number of Participants enrolled into Study at the Site(s) under the jurisdiction of the Veritas IRB:	
Total number of Participants withdrawn from Study at the Site(s) under the jurisdiction of the Veritas IRB :	

If any, please provide reasons for Participant withdrawal:

- ☐ Lack of Efficacy
- ☐ Adverse Event(s)
- ☐ Lost to Follow-Up (unable to contact Participant)
- ☐ Withdrew consent (Specify if any reason given):_____
- ☐ Other (Specify):_____

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4. STUDY PROTOCOL

What is the date of the Study Protocol currently in use, including any Amendments?	**Study Protocol:** _____/_____/_____ (DD MM YYYY) **Last Amendment:** _____/_____/_____ (DD MM YYYY)
Has there been any new information since the last approval which may impact the design of the Study Protocol (e.g. new scientific advances in this field of research, new relevant literature on this Study or the Investigational Product, interim research findings)?	☐ Yes ☐ No
If yes, please provide details and/or copies to the IRB:	

5. INVESTIGATOR'S BROCHURE

What is the date of the Investigator's Brochure currently in use, including any Amendments?	☐ Investigator's Brochure: _____/_____/_____ (DD MM YYYY) ☐ Last Amendment: _____/_____/_____ (DD MM YYYY) ☐ N/A (e.g. no product involved, approved product, medical device)

6. SAFETY AND COMPLAINTS

Since the last IRB review, has there been any suspected Non-Compliance (see attached glossary)? *If yes, attach a summary describing the nature of the suspected Non-Compliance.*	☐ Yes ☐ No
Since the last IRB review, has there been any other relevant information regarding this Study, especially information about risks associated with the Study or Study Product which may affect the willingness of Research Participants to continue to take part in the Study? *If yes, attach a copy or summary of this information.*	☐ Yes ☐ No
How many unexpected and related Serious Adverse Events were experienced in this Study at the Site(s) under the jurisdiction of the Veritas IRB in total?	
How many unexpected and related Serious Adverse Events were experienced in this Study at the Site(s) under the jurisdiction of the Veritas IRB since last approval?	

7. STUDY MONITORING

Is this Study supervised by a Data Safety Monitoring Board (DSMB)?	☐ Yes ☐ No
If yes, has the DSMB conducted a review of this Study that has not yet beensubmitted to the IRB? *If yes, please provide a copy of their Evaluation Letter(s).*	☐ Yes ☐ No
Since the last IRB review, did the Sponsor monitor the Study? *If yes, please provide details of the monitor's major findings, if any.*	☐ Yes ☐ No
Have there been any Multi-Center Trial Reports? *If yes, attach a copy of all Multi-Center Trial Reports.*	☐ Yes ☐ No

I certify that I have submitted all the required documentation and that the above information is accurate and truthful to the best of my knowledge.

Print Name

Signature _____ / _____ / _____ (DD MM YYYY)