



INSTITUTIONAL REVIEW BOARD

Form 3.4

FINAL REPORT

IRB Protocol No.		Initial Approval Date	
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Protocol Title	
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Principal Investigator			
Email		Mobile	

Study Sites			
Sponsor			
Sponsor Contact Person		E-mail	

1. Study Arms:	
2. Summary of Recruitment:	
Accrual ceiling set by REC	
• New participants accrued since last review	
• Total number of participants accrued since protocol began	
• No. of participants who are lost to follow up	
• No. of participants withdrawn from the study	
• No. of participants who experienced SAEs/SUSARs	
3. Number of participants who completed the study:	
4. Amendments to the original protocol (including dates of approval):	
5. Summary of onsite SAEs reported:	
6. Summary of participants' complaints or grievances documented regarding conduct of study:	
7. Summary of benefits to participants:	
8. Summary of indemnifications of study related injury (if applicable) :	
9. If terminated early, specify reason for termination	
10. Progress reports submitted (with dates of approval)	

