

**Institutional Review Board
Delaware State University IRB Committee**

*Office of Sponsored Programs
1200 N. DuPont Hwy.
Dover, DE 19901
Phone: (302) 857-6810
Fax: (302) 857-6804*

FINAL STUDY REPORT

Date of this report: _____ **Date approved by DSU-IRB** ____/____/____

Please read the instructions for each submission carefully. DSU's IRB will not accept incomplete submissions. Incomplete submissions will be returned to the principal investigator.

ADMINISTRATIVE INFORMATION		
Project Title:		
Principal Investigator:		Department:
Co-Investigators (list all)		Division:
Phone:	Fax:	Email:
Contact person for this study: (name/phone/fax/e-mail):		
Study personnel (list all – coordinators, data managers, etc.):		
Sponsor (if part of a funded research project):		

ENROLLMENT INFORMATION
Project Performance Period: ____/____/____
A. The original estimated number of subjects/patients to participate (signed consent, including screen failures) _____
B. The actual total number who completed the study: _____
C. The actual number dropped/withdrawn: _____

ADVERSE EVENTS/WITHDRAWAL FROM STUDY

Since the last IRB review, has any subject suffered any serious adverse events or unanticipated problems involving risk to subjects or others? If yes, specify the number of events and describe briefly their nature and significance. Were these reported to the IRB, to a sponsor, to the FDA or to anyone else?

How many of the recruited subjects at this site complained about any aspect of the study since the initiation of this project? _____ How was the complaint resolved? _____

Who did you contact about your complaint? _____

Did you remove any subject from the study due to adverse reactions, noncompliance or other reasons? If yes, please provide a description of the medical problem or other circumstances for each subject who was terminated involuntarily. _____

Did any subject voluntarily withdraw from the study for medical or non-medical reasons? If yes, please provide a description of any known reasons for those who withdrew. _____

STUDY RESULTS

Summarize any results (preliminary or final) obtained in the study. Please state whether the results to date have been consistent with what you expected. _____

INVESTIGATOR'S ASSURANCE

This progress report reflects the final/close-out status of the protocol.

Investigator's Signature

Date