



FINAL/STUDY COMPLETED REPORT

(to be submitted after ALL subjects have completed their final study visit)

Protocol Number: _____	Study Sponsor: _____		
Principal Investigator: _____			
_____	_____	_____	_____
<i>First Name</i>	<i>Middle Name</i>	<i>Last Name</i>	<i>Degree</i>
Study Title: _____			

Census Information

a. Number of subjects still actively participating or being followed in the study:	_____
b. Number of subjects who have completed the study:	+ _____
c. Number of subjects who have withdrawn or were discontinued from the study: <i>Attach a listing of withdrawn / discontinued subjects (Subject# only) and reasons for withdrawals /discontinuations</i>	+ _____
d. Number of subjects who were screen failures (consented but never randomized):	+ _____
e. TOTAL NUMBER OF SUBJECTS WHO HAVE BEEN CONSENTED IN THIS STUDY	= _____
f. Subjects consented by gender: Male:_____ Female:_____	

Serious Adverse Events

A serious adverse event (SAE), as defined by the FDA, is any Adverse Event that results in any of the following outcomes: death, a life threatening event, inpatient hospitalization or prolongation of an existing hospitalization, persistent or significant disability/incapacity, congenital anomaly/birth defect or important medical event. Any unanticipated risk or new information that may alter the risk / benefit ratio must be promptly reported to Aspire IRB to ensure the adequate protection of the welfare of the research subjects.

1. Did any SAEs occur at your site(s) for this study that have not been previously reported?
 Yes – *attach all unreported SAEs* No - *continue with question 2*
2. Did any significant protocol violations occur at your site for this protocol that have not been previously reported?
 Yes - *attach all unreported protocol violations* No

INVESTIGATOR COMPLIANCE STATEMENT

- As Principal Investigator of this study, I certify that:
- the information supplied on this form is correct;
 - no subjects are currently enrolled or actively being followed in this study; and
 - all study-related activities are complete at my site.

_____ <i>Signature of Principal Investigator</i>	_____ <i>Date</i>
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