



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c. Number of subjects who have withdrawn or were discontinued from the study: 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Attach a listing of withdrawn / discontinued subjects (Subject# only) and reasons for withdrawals /discontinuations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			
<i>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.</i>			
1. Did any serious adverse events or adverse events considered to be unexpected and related occur at your site for this study that have not been previously reported?			
<input type="checkbox"/> Yes – <i>attach all unreported SAEs</i> <input type="checkbox"/> No - <i>continue with question 2</i>			
2. Did any significant protocol violations occur at your site for this protocol that have not been previously reported?			
<input type="checkbox"/> Yes - <i>attach all unreported protocol violations</i> <input type="checkbox"/> 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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