

BCHS Central IRB Cover Sheet

IRB File #: _____ PI: _____ Central IRB Initial Approval Date: _____

Study Title: _____

Continuing Review:

Study Status: Active Closed to Accrual and Treatment Temp Closed to Accrual and Treatment

of subjects approved to be enrolled: _____ How many subjects signed consent: _____ How many subjects signed consent but did not meet criteria: _____ How many subjects are still active: _____

How many completed study: _____ How many subjects experienced an SAE: _____

Change in Procedure:

Type of Change: Addendum Amendment Modification Revised Protocol or Summary Revised ICF

Change in Investigator New Protocol Title IDB Other

Give brief description of the changes: _____

Serious Adverse Event:

SAE Category: Death Disability/Incapacity Life-Threatening to Subject or Others Hospitalization

Required Intervention SAE Associated with Test Article Not Previously Anticipated

Brief Description of the nature if the Serious Adverse Event: _____

Did you submit an SAE to Advarra that they say did not meet their requirements?: _____

Final Report:

of subjects approved to be enrolled: _____ How many subjects signed consent: _____ How many subjects signed consent but did not meet criteria: _____ How many completed study: _____ How many subjects experienced an SAE: _____

Reason for study closure: _____

Study Coordinator Signature: _____ Date: _____

Regulatory Associate Signature (If Applicable): _____ Date: _____