BCHS IRB Minimal Risk Progress Report

IRB File #: **PI:** **IRB Initial Approval Date:**

Study Title:

Study Status: ☐ Active ☐ Closed to Accrual and Treatment Date:_____ ☐ Temp Closed to Accrual and Treatment Date:_____

# 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: _____

Common Rule Changes to ICF **Yes:** **Date:** **No:**

Change in Procedure: # of CIPs since last yearly review: _____ Last FB CIP Date: _____

Type of Change: Addendum☐ Amendment Modification☐ Revised Protocol or Summary☐ Revised ICF ☐ Change in Investigator☐ New Protocol Title☐ IDB☐ Other☐ _____

Serious Adverse Event: # of SAEs since last yearly review: _____ Last SAE Date: _____

Last SAE Date Category: Death☐ Disability/Incapacity☐ Life-Threatening to Subject or Others☐ Hospitalization ☐ Required Intervention☐ SAE Associated with Test Article Not Previously Anticipated ☐

Deviation/Violation: # of Deviation/Violation since last yearly review:
IRB Date last Deviation/Violation was submitted: _____

Description of last Deviation/Violation:

FOR IRB USE ONLY:

Does **not** require yearly Continuing Review ☐ IRB Staff Initials: _____
Does require yearly Continuing Review ☐ IRB Staff Initials: _____ Date Contact Initiated: _____

Study Coordinator Signature: _____ Date: _____

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