Community Healthcare System Central IRB
Abbreviated Protocol Submission Form
(Form date 4/2017)

Reason for Submission	**IRB use only:**
Date submitted: ☐ Amendment: ☐ Data Safety Monitoring Committee ☐ Investigator Brochure: Submit IB electronically, **attach Summary of Changes** ☐ Sponsor Memorandums ☐ Site Audit Report ☐ Recruitment Material ☐ Other	IRB Number: Date Received:

NOTE: All questions must be answered in full. The response "see attached" will not be accepted and the form returned for clarification.

PART A-PROTOCOL INVESTIGATOR/COORDINATOR INFORMATION

Title of Study:
Version Date:
Principal Investigator:

Was this protocol reviewed by another IRB ☐ Yes ☐ No
If yes, specify and submit review:

PART B-LEVEL OF RISK/TYPE OF REVIEW REQUESTED

Level of Risk: ☐ Minimal ☐ More than Minimal

If the change affects the research design, does it carry enough likelihood of yielding data sufficient to warrant the risks to the subject? ☐ Yes ☐ No ☐ N/A

Type of Review Requested: ☐ Full Board ☐ Expedite ☐ Facilitated

PART C-DOCUMENTS TO BE REVIEWED

Please list any documents that must be listed on the approval letter

☐ Protocol version date:
☐ Investigator's Brochure version date:
☐ Investigator's Brochure Summary of Changes
☐ Amendment(s) List:
☐ Recruitment Materials List:
☐ Community Hospital Formatted Consent ***(submit 1 copy)***
☐ HIPAA Addendum (***submit 1 copy***)
☐ Other Consent Forms (***submit 1 copy***) List additional consents:
☐ Memorandums List:
☐ Patient Information Materials List:
☐ Other:

PART D-OVERVIEW/SIGNIFICANCE OF REQUESTED REVIEW

Provide brief overview of changes*:*

☐ New safety information that involves changes to risk/benefit ratio:
☐ Inclusion/Exclusion Changes:
☐ Editorial/Administrative Changes:
☐ Therapy Changes:
☐ Addition of Investigator: *Name:*
Submit CV and Medical Staff Credentials
☐ Other:
(e.g., closure, suspension, sub-study)

PART E-OVERVIEW OF ACTIONS TAKEN

Provide brief overview of actions.

☐ New Version Date:
☐ Hospital Formatted consent revised:
☐ HIPAA Addendum revised:
☐ Enrollment suspended pending approval of modification:
☐ Subjects to be re-consented following approval of informed consent:
☐ Other:

Principal Investigator (Typed)	Principal Investigator Signature	Date

NOTE: The CHS IRB requires the original signature of the Principal Investigator. Approval will not be sent to the Principal Investigator until the CHS IRB office has received the original signature on this document.