Community Healthcare System Central IRB
Request to Close a Research Study
(Form date 11/2017)

Date Submitted:	**IRB use only** 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.

Site(s) where research was performed: Please check all that apply
☐ Community Hospital
☐ Saint Mary Medical Center
☐ Saint Catherine Hospital

PART A-PROTOCOL/INVESTIGATOR/COORDINATOR INFORMATION

Title of Study:

Version date:

Principal Investigator:

PART B-REASON FOR REQUEST TO CLOSE

Provide explanation and communication from sponsor regarding closure (letter, e-mail, etc.) .
Project never initiated.
Slow/no accrual.
Completed per protocol.
Closed by sponsor.
Other:

Were all of the following submitted to the IRB? *If no, submit to IRB with explanation*.

- All Amendments ☐ Yes ☐ No ☐ N/A
- All Investigator Brochure Updates ☐ Yes ☐ No ☐ N/A
- All DSMB Reports ☐ Yes ☐ No ☐ N/A
- All Internal AEs/Unanticipated Events ☐ Yes ☐ No ☐ N/A
- All Protocol Deviations ☐ Yes ☐ No ☐ N/A
- All Subject Education/Recruitment Materials ☐ Yes ☐ No ☐ N/A
- All new risk or benefit information ☐ Yes ☐ No ☐ N/A
- All local site audits by sponsor ☐ Yes ☐ No ☐ N/A

PART C-RECRUITMENT/ENROLLMENT

Total number of subjects since initiation of protocol.

- Total number of subjects screened:
  CH _____ SMMC _____ SCH _____
- Total number of subjects enrolled:
  CH _____ SMMC _____ SCH _____
- Total number of subjects completed:
  CH _____ SMMC _____ SCH _____
- Total number of subjects withdrawn:
  CH _____ SMMC _____ SCH _____
- Total number of subjects lost to follow-up:
  CH SMMC SCH

For studies that are only registry or chart review in nature:

- Total number of subjects enrolled:
  CH _____ SMMC _____ SCH _____

Have there been any problems in assuring that subjects continue to receive medical treatment or appropriate follow-up after completion of study treatment?
☐ Yes ☐ No
If yes, provide explanation including attempted follow-up procedures:

During the study, were there any complaints from subjects relating to the study?
☐ Yes ☐ No
If yes, provide explanation of the complaints and resolution.

D-SUMMARY

Provide a summary of the conclusion and /or study findings. How will the study findings contribute to generalizable knowledge?

Is there continuing analysis of identifiable research data?
☐ Yes ☐ No

Is there continuing analysis of de-identified research data?
☐ Yes ☐ No

What are the plans for retaining or destroying the research data at your site?
Provide explanation:

NOTE: Researchers are reminded that subject permission must be obtained to retain identifiable private information and identifiable biospecimens for future research purposes. Researchers are also reminded that subject identifiers and the means to link subject names and codes with research data should not be stored on unencrypted moveable media (e.g., laptops, compact discs, jump drives)

E-QUALITY ASSURANCE

Were you satisfied with your experience with the CHS CIRB?
☐ Yes ☐ No
In no, provide an explanation as to what was unsatisfactory and what processes can be improved.

Certify that the above information has been reviewed by me and the co-investigators for the study and that the information is correct.

_____ _____
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.