Community Healthcare System Central IRB
Request to Renew a Research Study
(Form Date: 1/2019)

Date Submitted: ***Complete Summary of Clinical Trial Adverse Events Form for each subject enrolled in the trial since original approval (does not apply to Registry Studies)*** Appeal Closure: ☐ ***Complete Appeal of Closure Form***	**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 procedures are performed: Please check all that apply
☐ Community Hospital
☐ Saint Mary Medical Center
☐ Saint Catherine Hospital

Submit CHS CIRB Fee Invoice and check for $500.00 with submission for continuing review.

PART A-PROTOCOL/INVESTIGATOR/COORDINATOR INFORMATION

Title of Study:

Version date:

Principal Investigator:
*Address of Investigator:
*Phone number:
*e-mail address:

*Sub-Investigators:

Name of Clinical Coordinator:
*Address:
*Phone number:
*e-mail address

*Name(s) of Clinical Research Staff:

(*) Changes only

:

Submit a copy of <u>current</u> Curriculum Vitae and Credentials/Privileges (for all institutions if study conducted at more than one site) for <u>all new</u> investigators and clinical research staff.

Have there been any changes in staffing or scope of duties for investigators or clinical research staff since the last continuing review that you have not reported to the IRB?
☐ Yes ☐ No

PART B: CONFLICT OF INTEREST

Have **all new** Investigators and Key Personnel who will participate in the design, conduct, interpreting and reporting of research completed the required "Orientation of Investigators and Clinical Research Staff" education and return the signed Affirmation Statement and supporting documents prior to the submission of a protocol.
☐ Yes ☐ No

Do all Investigators and Key Personnel who participate in the design, conduct, interpreting and reporting of research have a current (within 1 (one) year of date of this submission) Financial Conflict of Interest Disclosure Form on file in the CHS CIRB office.
☐ Yes ☐ No

Have any of the Investigators and Key Personnel who participate in the design, conduct, interpreting and reporting of research discovered or acquired any new significant financial interest since last completing their Financial Conflict of Interest Disclosure Form on file.
☐ Yes ☐ No

If "Yes" provide an update Disclosure of Financial Interest Form.

If the CHS CIRB determines that a financial conflict of interest exists, the consent document must disclose this information either in the body of the document or by attaching a "Financial Conflict of Interest Disclosure Addendum".

PART C: STUDY STATUS

☐ Active (Enrolling new subjects)
☐ Ongoing, enrollment permanently closed, participants continue to receive protocol related treatment and collection of follow-up data continues
☐ Ongoing, enrollment permanently closed, all participants completed study treatment, the collection of follow-up data by the research department continues
☐ Research that has completed all intervention and follow-up and now only includes the analysis of data, even if the analysis involves identifiable biospecimens or information
☐ Research where all study-related interventions are completed and the remaining study activities only include accessing follow-up clinical data from clinical care procedures.
☐ Continuing review of research previously approved by the convened CHS CIRB may be eligible for expedited review where no subjects have been enrolled and no additional risks have been identified since the initial date of review and approval.

Did you adhere to all of the IRB Conditions of Approval received in the original approval or renewal letters?
☐ Yes ☐ No ☐ N/A
If no, provide explanation.

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 Protocol Deviations ☐ Yes ☐ No ☐ N/A
- All Internal AEs/Unanticipated Events ☐ Yes ☐ No ☐ N/A
- All Subject Education/Recruitment Material ☐ Yes ☐ No ☐ N/A
- All new risk or benefit information ☐ Yes ☐ No ☐ N/A
- All local site audits by sponsor ☐ Yes ☐ No ☐ N/A

Have there been any changes in the study that may have a fiscal impact on the Community Healthcare System?
☐ Yes ☐ No
If yes, provide explanation.

PART D; DOCUMENTS TO BE REVIEWED
List any documents that must be listed on the renewal letter

☐ Community Hospital Formatted Consent (*submit 2 copies*)
☐ HIPPA Addendum (*submit 2 copies*)
☐ Other Consent Forms (submit 2 copies) List:
☐ Other
☐ Other

PART E: LEVEL OF RISK ASSESSMENT

Has there been any change in the risk and benefit consideration of study participation as defined in the currently approved research protocol?
☐ Yes ☐ No
If yes, provide explanation:

Has new information been identified (e.g., risks or benefits) which would affect the willingness of current or future research subjects to participate in this research protocol?
☐ Yes ☐ No
If yes, provide information as to how it will be conveyed to both current and future research subjects. Are any newly identified risks addressed in the consent?

Have you become aware of any recent scientific publications that may potentially impact the continued conduct of this research study or the risk/benefit assessment that would affect the consideration of renewal of this research protocol?
☐ Yes ☐ No
If yes, provide explanation as to why this study should be renewed:

PART F: SUBJECT INFORMATION

*Complete a Summary of Clinical Trial Adverse Events form **for each subject enrolled** in the trial since the original date of approval (does not apply to Registry Studies; see below)*

1. Total number of subjects enrolled:
   CH _____ SMMC _____ SCH _____
2. Total number of subjects in the process of receiving study related treatment:
   CH _____ SMMC _____ SCH _____
3. Total number of subjects in follow-up, i.e. study related visits/calls requiring data collection only:
   CH _____ SMMC _____ SCH _____
4. Total number of subjects completed study; no further contact with the subject (does not include expired subjects)
   CH _____ SMMC _____ SCH _____
5. Total number of subjects that have expired
   CH _____ SMMC _____ SCH _____
6. Total number of subjects withdrawn: Provide an explanation of the circumstances for withdrawal on the *Summary of Clinical Trial Adverse Events* form (Does not include expired subjects)
   CH _____ SMMC _____ SCH _____
7. Total number of subjects lost to follow-up: Provide an explanation of the attempt (s) made to contact the subject on the *Summary of Clinical Trial Adverse Events* form
   CH _____ SMMC _____ SCH _____
8. Number of subject complaints: Provide an explanation of the nature of the complaint and how the matter was resolved on the *Summary of Clinical Trial Adverse Events* form
   CH _____ SMMC _____ SCH _____

NOTE: Lines 4 + 5 + 6 + 7 + 8 + 9 should equal (=) the Total Number of Subjects Enrolled (Line 1)

Registry studies or Retrospective Chart Review

For studies that are only registry or chart review in nature: (Do not complete a Summary of Clinical Trial Adverse Events Form)

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

Were any subjects who could be identified as "vulnerable" consented to participate in the study since the last review? (Not specifically included in the design of the study)

☐ Yes *specify* ☐ No

☐ Children
☐ Pregnant women
☐ Nursing home residents
☐ Employees
☐ Educationally disadvantaged
☐ Terminally ill
☐ Low Literacy or Blind **
☐ Prisoners
☐ Decisionally impaired individuals
☐ Homeless
☐ Students
☐ Economically disadvantaged
☐ Limited English Proficiency **
☐ Deaf **

Describe additional safeguards used to protect vulnerable subjects from coercion and undue influence:

Was surrogate consent obtained for any subject?
☐ Yes ☐ No
If yes, describe the consent process for each subject:

Was the short form consent or a translated version of the CHS CIRB consent used for any subject?
☐ Yes ☐ No
If yes, describe the consent from process for each subject:

Did all research subjects give written informed consent?
☐ Yes ☐No ☐ N/A

a. If No or N/A, provide explanation (i.e., waiver of documentation of informed consent, surrogate consent, assent, no subjects enrolled).

b. If Yes:
   - Was informed consent obtained prior to conducting any study-related procedures? ☐ Yes ☐ No
   - Have copies of the signed consent form been filed in the subject's medical/research record, with the investigator's files, and a copy provided to the subject? ☐ Yes ☐ No
   - Did you make any changes to the consent form that were not reviewed and approved by the IRB? ☐ Yes ☐ No

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, give brief explanation including attempted follow-up procedures:

PART G: APPEAL OF CLOSURE

NOTE: If the study has failed to accrue subjects within 2 years of initiation, the investigator must provide a justification as to why this research should be continued. The *Appeal of Study Closure form* can be accessed on the Intranet and Internet and must accompany the *Request to Renew a Research Study.*

PART H: CONFIDENTIALITY

Provide an explanation of the methods used by the investigator's office to store and send study date, i.e. computer, fax, paper files, and the safeguards employed to ensure confidentiality of personal health information.

NOTE: Researchers are reminded that subject permission must be obtained to retain personally identifiable research data 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, smart phones, compact discs, jump drives)

PART I-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.

I certify that the above information has been reviewed by me and the co/sub-investigators for the study and that the information is correct.

_____ _____
Signature of Principal Investigator Date

NOTE: The CHS C IRB requires the original signature of all the investigators. The CHS CIRB office will return all incomplete submissions. The submission will not appear on the meeting agenda until the CHS CIRB office has complete submission packet.