Community Healthcare System Central IRB
Facilitated Protocol Submission Form
Review for Local Context
(Form Date: 7/2021)

Date Submitted: New Protocol: ☐	**IRB use only** IRB Number: Date received:

NOTE: To be completed when the CHS CIRB is not intended to be the Reviewing IRB.

Request to change the Reviewing IRB

Specify External IRB:

☐ NCI CIRB
☐ Carle Cancer Center NCORP
☐ SMART IRB
☐ Other: List Click or tap here to enter text.

Site(s) where research procedures will be performed. Research procedures may include but are not limited to: consent of subjects, administration of investigational treatment, documentation of research procedures:
Check all that apply:

☐ Community Hospital
☐ Saint Mary Medical Center
☐ Saint Catherine Hospital
☐ Other *specify*:

PART A-PROTOCOL INFORMATION

Title of Study:

Version date:

PART B – INVESTIGATOR/COORDINATOR INFORMATION

Principal Investigator:

Co-Investigators:

Does the protocol require the investigators to apply for any additional investigator privileges or credentials? ☐ Yes ☐ No

If yes, has the Investigator initiated a request for additional privileges to Medical Staff Services and the Credentialing Committee? ☐ Yes ☐ No

Does the protocol require additional training, monitoring or proctoring of the investigators during the implementation of the study? ☐ Yes ☐ No

If yes, provide an explanation of the protocol requirements:

Name of Clinical Research Coordinator:

Submit List of Study Team: (Key Personnel who will participate in the design, conduct, interpreting and reporting of research)

PART C –EDUCATION/CONFLICT OF INTEREST REQUIREMENTS

Do not submit documentation. Documents to be available up request.

Have all 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 (including a CHS CIRB Financial Conflict of Interest Disclosure form) prior to the submission of the protocol?

☐ 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 the CHS CIRB Financial Conflict of Interest Disclosure Form on file?

☐ Yes ☐ No

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 D- REVIEW OF PROTOCOL

Was this protocol reviewed by the appropriate system research committee?

☐ Yes ☐ No ☐ NA

Was this protocol approved by Administration?

☐ Yes ☐ No

PART E-SPONSOR/SOURCE OF FINANCIAL SUPPORT

Indicate all applicable sources of support and the sponsor:

☐ Federal – Sponsor:
Awardee Institution:
☐ Commercial – Sponsor:

NOTE: The source and type of financial support to the institution and the investigator must be indicated on the Investigational Consent document.

PART F-DOCUMENTS TO BE SUBMITTED/REVIEWED

☐ Most recent version of the study protocol with appendices
☐ Most recent External IRB initial or continuing review approval letter with protocol expiration date
☐ Informed Consent Form (S**ubmit 1 copy**)
☐ HIPAA Authorization (S**ubmit 1 copy**)
☐ Financial Interest Disclosure Addendum (**Submit 1 copy**)
☐ Other Consent Forms (**Submit 1 copy**) List additional consents:

PART G-STUDY DESIGN/SIGNIFICANCE OF PROTOCOL

Duration of Study per Subject: _____ Duration of Entire Study: _____

PART H-RECRUITMENT INFORMATION

What methods of recruitment will be employed during the study? Provide explanation. Click or tap here to enter text.

Will you require a "Waiver of HIPPA Authorization" to be able to access medical record information prior to obtaining a signed investigational consent and HIPPA Authorization?
☐ Yes ☐ No

NOTE: The Waiver of HIPAA Authorization Request may be downloaded from the Intranet.

Does the study design specifically include vulnerable subjects?

☐ 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 *

* Refer to IRB Policy #15.1 Barriers To Informed Consent for consent requirement
*Refer to Language Access Policies for assistance in locating certified medical interpreter assistance.

If the study design specifically includes vulnerable subjects, describe any additional safeguards used to protect them from coercion or undue influence. Click or tap here to enter text.

Does the study design specifically exclude a population of subjects, for example, gender, ethnicity, cultural, or due to language barriers? ☐ Yes ☐ No

If yes, provide an explanation of the justification for the exclusion of these subjects. Click or tap here to enter text.

Have all recruitment materials, websites, and subject education materials been reviewed by the Reviewing IRB? ☐ Yes ☐ No
If no, submit additional materials

PART I – CONSENT PROCESS

Who are the individuals that have been designated to conduct the consent process? (As listed on the study's Responsibility Log)

Have these individuals received specific training to conduct the consent discussion?
☐ Yes ☐ No
If No, describe plan to train these individuals. Click or tap here to enter text.

PART J-RESEARCH COSTS

Have the financial obligations/liability of the subject, the sponsor and the institution been reviewed? ☐ Yes ☐ No

Have the potential costs of the study that will be the responsibility of the patient been reviewed for potential coverage by their insurance carrier and/or Medicare? ☐ Yes ☐ No

PART K-ADDITIONAL APPROVALS REQUIRED

Does this study involve the participation of any ancillary departments? ☐ Yes ☐ No

Have the appropriate departments been approached to discuss the level of support required for the study? ☐ Yes ☐ No

☐ Administration Contact:_____
☐ Lab Contact: _____
☐ Cath Lab Contact: _____
☐ PCS Contact: _____
☐ Radiology Contact: _____
☐ Pharmacy Contact: _____
☐ Other *Specify* Contact: _____

Administrative review of contract required for all studies conducted within a CHS Entity: See Budget Worksheet and Clinical Research Policy "Clinical Research Agreement Review for Research Conducted within a CHS Entity" CLR 9

PART L-CONFIDENTIALITY

Describe how you will keep research data sets secure and protected from improper use and disclosure in terms of the following:

i. Where will data files be stored (even temporarily) during the research process?

Electronic files:
☐ Secure CHS network share drive
☐ CHS desktop/lap computer
☐ CHS-encrypted thumb drive/portable media (Contact IT for questions on encryption)

Paper files:

☐ Locked file cabinet
☐ Locked office

☐ Other: Provide explanation:

ii. How will data files be secured"

☐ Password protected files
☐ Other: Provide explanation:

Will the subjects' identity be disclosed in the event of publication or sharing of data?
☐ Yes ☐ No If Yes, provide explanation: Click or tap here to enter text.

Will PHI be disclosed for purposes other than for research?
☐ Yes ☐No If Yes, provide explanation: Click or tap here to enter text.

NOTE: Subject consent must be obtained to retain personally identifiable research data for future research purposes. Data that contains 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)

CERTIFICATION OF INVESTIGATOR RESPONSIBILITIES

By signing below I agree/certify that:

1. I have reviewed this protocol submission in its entirety and that I am fully cognizant of, and in agreement with, all submitted statements.
2. I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.
    - I will notify the CHS IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.
    - I will request and obtain CHS IRB approval of any proposed modification to the research protocol or informed consent document(s) prior to implementing such modifications.
3. I have verified that all of the co-investigators and other personnel, assisting with the conduct of this research, myself included, have fully disclosed all current and potential conflicts of interest and will disclose all conflicts of interest acquired in the future to the CHS CIRB in accordance with the policy, IRB 2; Conflicts of Interest in Research.
4. I will ensure that all co-investigators, and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (d) adverse event reporting requirements; (e) data and record-keeping requirements, and (f) the current CHS CIRB approval status of the research study.
5. I will not enroll any individual into this research study: (a) until such time that the conduct of the study has been approved in writing by the IRB; (b) during any period wherein CHS CIRB renewal approval of this research study has lapsed: (c) during any period wherein CHS CIRB approval of the research study or research study enrollment has been

suspended, or wherein the sponsor has suspended research study enrollment; or (d) following termination of CHS CIRB approval of the research study or following sponsor/principal investigator termination of research study enrollment.

6. I will respond promptly to all requests for information or materials solicited by the CHS CIRB office.
7. I will submit the research study in a timely manner for CHS CIRB renewal approval.
8. I will not enroll any individual into this research study until such time that I obtain his/her written informed consent, or, if applicable, the written informed consent of his/her authorized representative (i.e., unless the CHS CIRB has granted a waiver of the requirement to obtain written informed consent).
    - I will employ and oversee an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of these research procedures, the financial responsibilities of participating in the research study and their rights as a research study volunteer.
9. I will ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.
10. I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risks/benefit ratio of research study participation.
11. I am cognizant of, and will comply with current federal regulations and CHS CIRB requirements governing human subject research including adverse event reporting requirements.
12. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.
13. I will ensure that the conduct of this research study adheres to the Good Clinical Practice Guidelines.

_____	_____	_____
Principal Investigator Name (Print)	Principal Investigator Signature	Date

NOTE: The CHS C IRB will accept a faxed or scanned copy of the document containing the original signatures.