Community Healthcare System Central IRB
Protocol Submission Form
(Form Date: 7/2021)

Reason for Submission: Date Submitted: New Protocol: ☐ IND/IDE number for investigational drug/device:	**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 will be performed: Check all that apply:
☐ Community Hospital
☐ Saint Mary Medical Center
☐ Saint Catherine Hospital
☐ Other *specify*:

Submit CHS CIRB Fee Invoice and check for $2,000 with submission for initial review.

PART A-PROTOCOL INFORMATION

Title of Study:

Version date:

Original date of approval:

Is the research activity FDA regulated? ☐ Yes ☐ No

Does the proposed activity involve obtaining information about living individuals?
☐ Yes ☐ No

Does the activity involve intervention or interaction with the individuals (i.e., prospective collection of data/specimens? ☐ Yes ☐ No

Does the proposed activity involve analysis of existing data and/or specimens? Existing specimens include those that are already in existence at the time of the proposed research and specimens that will be collected in the future for purposes other than the currently proposed research (i.e., ongoing collection of specimens for a tissue repository located within the CHS System) ☐ Yes ☐ No

PART B – INVESTIGATOR/COORDINATOR INFORMATION

Principal Investigator:

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

Co-Investigators:

Sub-Investigators:

Submit a copy of current Curriculum Vitae and Credentials/Privileges (for all institutions if study conducted at more than one site) for all 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:

NOTE: Documentation of additional training, monitoring or proctoring must be submitted to the CHS CIRB when complete.

Name of Clinical Research Coordinator:
Submit a copy of current Curriculum Vitae and Credentials/Privileges (if applicable, for all institutions if study conducted at more than one site)

Name (s) of Clinical Research Staff:

Submit a copy of current Curriculum Vitae (s) and Credentials/Privileges (if applicable, for all institutions if study conducted at more than one site) for all Clinical Research staff

PART C –EDUCATION/CONFLICT OF INTEREST REQUIREMENTS

Have all Investigators and Key Personnel who will participate in the design, conduct, interpreting and reporting of research completed the required human subjects research protection education, 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".

All documentation must be made available to the CHS CIRB upon request.

PART D- TYPE OF REVIEW REQUESTED

Was this protocol reviewed by the appropriate system research committee?

☐ Yes ☐ No ☐ NA

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

PART E-SPONSOR/SOURCE OF FINANCIAL SUPPORT

Indicate all applicable sources of support and the sponsor:

☐ Federal – Sponsor:
Awardee Institution:
Submission of copy of the grant is required
☐ Commercial – Sponsor:
☐ Foundation – Sponsor:
☐ Other (specify) – Sponsor:
☐ No Support

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

PART F-DOCUMENTS TO BE SUBMITTED/REVIEWED

List all documents as they must appear on the approval letter

☐ Protocol version date:
☐ Consent version date, if different from protocol date:
☐ Investigator's Brochure version date:
(Submit 1 copy)

NOTE: IBs may be submitted electronically following the initial review and approval of the protocol. An Abbreviated Submission form and a paper copy of the IB Summary of Changes still must accompany the electronic submission.

☐ Amendment (s) (**List):**
☐ Recruitment Materials (**List)**:
☐ CHS Formatted Consent (S**ubmit 2 copies**)
☐ HIPAA Addendum (**submit 2 copies**) (**NOTE:** Additional Addendum not required if information is contained in the body of the Investigational Consent)
☐ Financial Interest Disclosure Addendum (**Submit 2 copies**)
☐ Other Consent Forms (**submit 2 copies**) List additional consents:
☐ Requesting Waiver of Informed Consent
☐ Requesting Waiver of Documentation of Informed Consent
☐ Memorandums **List**:
☐ Subject Information/Recruitment Materials **List**:
☐ FDA letter authorizing IDE
☐ 510 (k) letter
☐ Additional information from sponsor supporting investigational device
☐ Other:
☐ Other:

PART G-STUDY DESIGN/SIGNIFICANCE OF PROTOCOL

Provide discussion of the scientific significance and goal of the protocol.

Assessment of the Level of Risk: ☐ Minimal ☐ More than Minimal

Does the research design carry enough likelihood of yielding data sufficient to warrant the risks to the subject? Provide explanation.

Provide an explanation of the precautions taken to minimize risks to the subject.

Have adequate safeguards been taken regarding reproductive risk? ☐ Yes ☐ No ☐ NA
If "Yes", is the same language in the investigational consent? ☐ Yes ☐ No
Provide explanation.

Provide a discussion of the inclusion/exclusion criteria for subject entry or for use of data/tissues.

Provide a justification for the use of a placebo, if applicable.

Does the research design reflect current practice? ☐ Yes ☐ No

Is this protocol similar in design to currently approved protocols? ☐ Yes ☐ No
If yes, list protocol(s).

If yes, should this protocol replace the current protocol? ☐ Yes ☐ No

Is it possible for the subject to receive the same medication/device if they do not participate in this protocol? ☐ Yes ☐ No

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

Is there an independent Data Safety Monitoring Board to review this protocol for safety and adherence to the study protocol? ☐ Yes ☐ No

Provide an explanation regarding the potential direct benefit, if any, to the subjects.

How is the cost and/or the availability of the drugs/device addressed both during the study and after the study is completed? Provide an explanation

PART H-RECRUITMENT INFORMATION

Is this a multi-center study?

☐ Yes Indicate total number of subjects to be enrolled at multi-center sites: _____

☐ No

What is the total number of subjects that have been enrolled in the study at all sites since its original date of approval? : _____

What is the total number of patients that have been treated for the disease state addressed in the protocol within the Community Healthcare System that may benefit from participation in this study? For example: The protocol addresses free cell renal carcinoma. How many cases of free cell renal carcinoma were reviewed by the Tumor Board in the last 12 calendar months? _____

Does the research design carry enough likelihood of accruing a sufficient number of subjects to warrant initiation at this site? Provide explanation:

Approximately how many subjects are expected to be enrolled within the Community Healthcare system? _____

Gender: ☐ Male ☐ Female Age range of all subjects: _____

Does the study design specifically include vulnerable subjects?

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

* Refer to IRB Policy #15.1 Barriers To Informed Consent for consent requirements

If the study design specifically includes vulnerable subjects, describe any additional safeguards used to protect them from coercion and undue influence.

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

If yes, provide an explanation of the justification for the exclusion of these subjects.

What methods of recruitment will be employed during the study? Provide explanation.

Will this study employ the use of a Web site or other means of recruiting study subjects?
☐ Yes ☐ No
If yes, list:

Has the Web site or recruitment materials been reviewed by the CHS CIRB prior to this submission?
☐ Yes ☐ No
If no, submit recruitment materials for review.

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)

Did these individuals receive training specifically in how to conduct the consent discussion? Provide an explanation:

Provide an explanation as to how and where the consent process will take place.

Will the study require the use of a translated version of the consent? ☐ Yes ☐ No
If yes, provide 2 copies of the consent and documentation of the interpreter's credentials.

Will the study require the use of a Short Form Consent? ☐ Yes ☐ No
If yes, provide an explanation to justify the use of the Short Form Consent.

PART J-RESEARCH COSTS

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

Has the contract with the Sponsor been approved? ☐ Yes ☐ No
If no, what is the anticipated approval date?

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

PART K-ADDITIONAL APPROVALS REQUIRED

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

NOTE: Research that has been approved by the CHS CIRB may be subject to further review and approval or disapproval by officials of the institution, but those officials may not approve the research if it has not been approved by the CHS CIRB.

PART L-CONFIDENTIALITY

Indicate which of the following applies to the research activity;

1. ☐ Only de-identified specimens and/or data will be obtained. Indicate which of the following circumstances applies;

☐ PI and holder of the re-identification key enter into an agreement prohibiting the release of the key to the PI or other research personnel under any circumstances

☐ De-identified specimens or data will be provided. The PI will not request PHI or re-identification

☐ Investigators will record data without identifiers

☐ Yes ☐ No Regarding the release of specimens, has a Material Transfer Agreement been completed? The use of an MTA is generally needed for the transfer of human biological materials and associated information obtained as a) leftover (or remnant) materials collected in the course of medical treatment, testing or clinical research; b) additional or "secondary specimens collected in the course of conducting a clinical trial, with consent by the subject; or c) voluntarily provided by a donor for banking and general research use".

2. ☐ A limited data set will be obtained. A limited data set means the only identifiers in the data set are elements of date (e.g., date of birth, date of diagnosis) or broad geographic data (e.g., town, state, zip code, but not street address).

☐ Yes ☐ No Will the limited data set be obtained from an Honest Broker?

i. If NO, who will complete the limited data set?

☐ Yes ☐ No Has a Data Use Agreement (DUA) been completed?

3. ☐ Data will be obtained or recorded with identifiers (any of the 18 PHI Identifiers) either directly on the data collection sheet or indirectly by coding (linking) study data to subject identifiers.

i. Describe the plan to destroy/remove all identifiers, including all elements of dates, from data files as early as possible with the research process.

ii. Identify at which point of the research process all identifiers, including all elements of dates, will be destroyed/removed:
☐ After data collection is completed
☐ Prior to data analysis
☐ After data analysis
☐ Prior to submittal for publication
☐ After publication has been accepted
☐ Other: specify;

4. If you checked "3" above, provide the following information:

a. 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:

b. Will the subjects' identity be disclosed in the event of publication or sharing of data? ☐ Yes ☐ No

i. If Yes, provide explanation:

c. Will PHI be re-used or disclosed for purposes other than research use?
☐ Yes ☐ No

i. If Yes, provide explanation:

d. List any outside entities (i.e., collaborators, sponsor, regulatory agency, data management, etc.) to whom PHI will be disclosed, which includes any elements of dates. Provide an external Data Use Agreement for each outside entity listed if the data use language is not contained within the Investigator Agreement or Contract.

NOTE: Researchers are reminded that subject consent 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)

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
Sub-Investigator Name (Print)	Sub-Investigator Signature	Date
Sub-Investigator Name (Print)	Sub-Investigator Signature	Date
Sub-Investigator Name (Print)	Sub-Investigator Signature	Date

Sub-Investigator Name (Print)	Sub-Investigator Signature	Date
Sub-Investigator Name (Print)	Sub-Investigator Signature	Date
Sub-Investigator Name (Print)	Sub-Investigator Signature	Date
Sub-Investigator Name (Print)	Sub-Investigator Signature	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.