Community Healthcare System Central IRB
Modification & Event Reporting Submission Form
External IRB

(Form Date: 6/2021)

Instructions

This form is to be used for subsequent submissions for any study being conducted within the Community Healthcare System or one of its affiliate institutions that is under the oversight of an external IRB (any IRB that is not the CHS CIRB).

Submit this completed form, along with the required documentation as instructed. Modifications and event reports will receive a letter of acknowledgement from the CHS CIRB Office following a review. The CHS CIRB will be notified of these actions as an agenda item at the next convened meeting.

Part A-Protocol Information

Title of Study: Click or tap here to enter text.

The IRB currently serving as the External or IRB of Record:

- ☐ Carle Foundation IRB
- ☐ SMART IRB
- ☐ NCI CIRB
- ☐ Other: Name: Click or tap here to enter text.

Principal Investigator: Click or tap here to enter text.

Part B – Submission Details

Submission Details: Select all that apply and complete the applicable sections.

Key Personnel Change	☐ Complete Section C
Negative actions taken by a government oversight office	☐ Complete Section D
Substantial changes to the study	☐ Complete Section E
Adverse Events	☐ Complete Section F
Protocol Deviations	☐ Complete Section G
Study Completed	☐ Complete Section H
PI Attestation – **Required**	☐ Complete Section I

Section C – Key Personnel Changes

☐ Addition of Key Personnel	Name: Click or tap here to enter text. Research Role: Click or tap here to enter text. Following must be on file in research office and available upon request. CHS CIRB Orientation Affirmation Statement ☐ Yes ☐ No Current CITI Training (or equivalent) ☐ Yes ☐ No Financial Conflict of Interest Statement ☐ Yes ☐ No Confidentiality Statement ☐ Yes ☐ No CV and Credentials ☐ Yes ☐ No
☐ Removal of Key Personnel	Name: Click or tap here to enter text. Research Role: Click or tap here to enter text.
☐Change of PI	Name of current PI:Click or tap here to enter text. Include statement from the current PI acknowledging that a PI change is appropriate: ☐ Statement from current PI included
☐ Proposed new PI	Name of proposed new PI: Click or tap here to enter text. Following must be on file in research office and available upon request. CHS CIRB Orientation Affirmation Statement ☐ Yes ☐ No Current CITI Training (or equivalent) ☐ Yes ☐ No Financial Conflict of Interest Statement ☐ Yes ☐ No Confidentiality Statement ☐ Yes ☐ No CV and Credentials ☐ Yes ☐ No

Section D – Report of Actions taken by a government oversight office

Submit a copy of the report that was submitted to the External IRB or the local research site

☐	OHRP Determination Letter
☐	FDA Warning Letter
☐	FDA 483 Inspection Reports with official action
☐	FDA Restrictions placed on IRBs or investigators
☐	Compliance Actions taken under non-US authorities related to human research protections
☐	Other – Provide explanation and report Click or tap here to enter text.

Section E – Substantial changes to the study that may significantly affect the health and safety of the local research subjects

Submit a copy of the memorandum that was received from the External IRB

☐	Study suspended
☐	New risk information that would require re-consent of the subjects

☐	Changes to research related injury language
☐	Changes to research related costs for the subject
☐	Other: Click or tap here to enter text.

Section F – Adverse Events

Only submit those Adverse Events for Local Subjects that can be "Definitely" or "Probably" attributed to the subject's participation in the study. Include a copy of the report that was submitted to the External IRB.

Unanticipated Problem/Adverse Event			
Subject ID	**Date of Event**	**Causality**	**Severity**
Click or tap here to enter text.	Click or tap here to enter text.	☐ Definite ☐ Probable	☐ Serious Unexpected ☐ Serious Expected ☐ Moderate Unexpected ☐ Moderate Expected
Subject ID	**Date of Event**	**Causality**	**Severity**
Click or tap here to enter text.	Click or tap here to enter text.	☐ Definite ☐ Probable	☐ Serious Unexpected ☐ Serious Expected ☐ Moderate Unexpected ☐ Moderate Expected

Section G: Protocol Deviations

Include a copy of the report that was submitted to the External IRB.

Subject ID	Date of Event	Describe steps to prevent future events
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

Section H: Study closed with External IRB

Include a copy of the letter received from the sponsor

Effective date: Click or tap here to enter text.

Section I: Principal Investigator Attestation

By signing the description of this research project, the Principal Investigator:

1. Attest to the accuracy of the information provided;
2. Agrees to accept primary responsibility for the scientific and ethical conduct of the research, as approved by the IRB;
3. Agrees to abide by the IRB's policies and procedures;
4. Agrees to submit adverse event reports within the time frame prescribed in policy; and
5. Agrees to abide by the investigator responsibilities in the Reliance Agreement.

Signature of the Principal Investigator | Printed Name | Date