Community Healthcare System Central IRB
Application/Report for the Emergency/Compassionate Use of a Test Article
(Form Date 11/2017)

Date Submitted: Report of use by the Physician/Investigator: ☐ Application for use by the Physician/Investigator: ☐ Application for "off label" planned use of a device: ☐ Independent Physician Reviewer Concurrence: ☐	**IRB use only** **IRB number:** **Date Received:**

Form Instructions:

- A copy of this form must be completed and signed by the Principle Investigator, the Physician/Investigator and the Independent Physician Reviewer.
- The Principle Investigator must inform the CHS CIRB within five (5) working days of emergency use of a test article.

Additional Documentation to be submitted:

- Informed Consent or Patient Information Sheets
- Copies of documentation sent to Sponsor

Principal Investigator:
Address:
Phone Number:
E-mail address:

Physician/Investigator applying for use of the test article:
Note: Credentials must be on file with CHS CIRB as part of the original approval.
Address:
Phone Number:
E-mail address:

Independent Physician Reviewer:
Address:
Phone Number:
E-mail address:

1. Name of test article:

2. Title of Study:

3. Is this test article regulated by the FDA? ☐ Yes (Complete this section); ☐ No

   A. ☐ This study involves a drug or biologic: IND#, if applicable:
   Study is: ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Treatment

   B. This study involves a device: IDE#, if applicable:

   The device is: ☐ Significant Risk ☐ Non-Significant Risk
   The device is: ☐ Investigational ☐ Marketed

C. Who is the Sponsor/Holder of the IND/IDE?

D. The Sponsor/ IDE Holder has been notified of the intended use or the use of the device. ☐ Yes ☐ No
If Yes, attach copies of documents.
If No, Principal Investigator must notify Sponsor/IDE Holder according to their notification requirements.

F. How did the physician/investigator gain possession of the test article?

G. What is the intended (on label) use of the test article? *Specify dosage, route of administration or application, frequency, total duration of use.*

4. Patient Name:

5. Medical Record Number:

6. Date of Use or Intended Use:

7. Description of use or planned use of test article:

A. Diagnosis:

B. Why was the condition considered life threatening, i.e. necessitating use of the test article? *Note that having an ultimately fatal condition does not constitute a life threatening condition.*

C. What made the physician(s) conclude that there was no generally recognized standard acceptable treatment or therapy available, so that this investigational treatment was offered?

D. Provide explanation as to why there was not sufficient time to obtain full CHS CIRB or FDA approval.

E. How did the use to the test article (off label) differ from the intended use (on label)?

F. Identify the risks involved, known and potential?

G. What type of informed consent process was implemented prior to the use of the test article?

H. Was the patient/patient's legal representative able to give informed consent?
☐ Yes ☐ No
If Yes, attach copy of signed informed consent.
If No, provide explanation of reason patient was not able to give informed consent and who did provide consent for treatment.

I. Was the patient informed of the "off label" use of the test article?
☐ Yes ☐ No

If No, provide explanation.

J. Provide an explanation of the plan to continue to monitor the patient's progress following use of the test article?

8. If the interval between the date of initial use of the test article and the date of submission of this application is more than five (5) days, provide an explanation for the delay.

Statement of Assurance by Principal Investigator

I certify that the information provided in this report is complete and accurate.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to the study protocol and any stipulations imposed by the Community Healthcare System Central Institutional Review Board.

I understand that the test article is expected to be administered to a single patient as a single course (may involve multiple dosing to achieve maximal efficacy). The patient to receive the test article should not be enrolled in a research study related to the test article. **If subsequent use of the test article is contemplated in the same patient or in others, a new protocol submission to the CHS CIRB is required in advance of that use.**

I understand that information from this case will not be collected or used for any research purposes.

I agree to comply with all of the policies and procedures of the CHS CIRB and Community Healthcare System as well as with all applicable federal, state, and local laws regarding the protection of human participants.

_____ _____

Principal Investigator Date

_____ _____

Physician/Investigator (administering test article) 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.

To be completed by Independent Physician Reviewer

1. Does the use the test article meet;
☐ The definition of the approved use of the test article under the HUD?
☐ The definition of an "off-label" (not approved use) of the test article under the HUD?

2. Could the use of the test article be assessed as fitting the description of "emergent"? Check all that apply.
☐ Patient had a life threatening condition necessitating the use of the test article;
☐ No standard acceptable treatment was available;
☐ There was not sufficient time to obtain prior approval of the test article.

3. If the use of the test article does not meet the definition for approved use under the HUD nor was the use assessed as being an "emergent off-label use", was there an alternative device or procedure that could have been employed for this patient?
☐ Yes ☐ No
If yes, provide an explanation for the use of the alternative device or procedure

The Independent Physician Reviewer will document their determination by checking one of the options below.

The Independent Physician Reviewer:
☐ Has reviewed and concurs with the emergent use of the test article.
☐ Has reviewed and does not concur with the emergent use of the test article. *Provide explanation.*

OR

☐ Has reviewed and concurs with request for the planned "off label" use of the test article.
☐ Has reviewed and does not concur with request for the planned "off label" use of the test article. *Provide explanation*.

_____ _____
Independent Physician Reviewer 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.

For CHS IRB Use Only

☐ Has reviewed and concurs with the emergent use of the test article.
☐ Has reviewed and does not concur with the emergent use of the test article. *Refer to appropriate research committee for review.*

OR

☐ Concurs with request for the planned "off label" use of the test article.
☐ Does not concur with request for the planned "off label" use of the test article. *Provide explanation*.

_____	_____
Chair, CHS CIRB	Date
_____	_____
Vice-Chair, CHS CIRB, if applicable	Date
_____	_____
Second Independent Physician Reviewer, if applicable	Date