TITLE: Emergency or Compassionate/Humanitarian Use of a Test Article		POLICY/PROCEDURE NUMBER: IRB 16	
Author:	Jana L. Lacera, RN, MSA, CDM	Applicable To:	CHS CIRB
Supersedes:		Issued By:	CHS CIRB
Date Originated:	4/28/05	Date Effective:	6/2020
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	CFNI		Community Hospital		St. Catherine Hospital		St. Mary Medical Center
X	Munster, Indiana	X	Munster, Indiana	X	East Chicago, Indiana	X	Hobart, Indiana

POLICY/PROCEDURE STATEMENT/PURPOSE:

Federal regulations for the protection of human subjects do not permit research activities to be started without prior IRB review and approval. These regulations, however, do not limit or interfere with the authority of a physician to provide emergency medical treatment for patients, subject to FDA requirements for release and emergency use of an unapproved drug, biologic, or device on a single patient.

When prior CHS CIRB approval has not been obtained, the patient may not be considered a research subject and data regarding treatment or outcome may not be included in any report of research activity. (21 CFR 312.34)

The use of a test article in an investigation designed to be conducted under emergency conditions (e.g., emergency room research) usually does not qualify for the emergency use exemption.

DEFINITIONS:

Emergency Use: The use of a test article (e.g., investigational drug, biologic, or device) on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval for the use. The emergency use exemption requires that all of the following conditions be met:

a. Subject has a life threatening condition necessitating use of the test article.
b. No standard acceptable treatment is available.
c. There is not sufficient time to obtain full CHS CIRB approval.

The Principal Investigator shall report in writing the emergency use of the test article within five (5) working days to CHS CIRB Chair or the Human Protections Administrator.

Emergency Use of a Test Article Without Informed Consent: In emergency use situations, an investigator is required to obtain informed consent of the subject unless the investigator can certify in writing to the following:

a. The subject is confronted by a life-threatening situation necessitating the use of the test article.
b. Informed consent could not be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
c. Time was not sufficient to obtain consent from the subject's legally authorized representative.
d. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

Independent Physician Reviewer: A licensed physician who is a member of or consultant to the CHS CIRB and who is not otherwise participating in the clinical investigation or care of the patient
For the purposes of this policy and to ensure a prompt response, an Independent Physician Reviewer could be:

- Chair of the CHS CIRB
- Physician member of the CHS CIRB
- Chair of the Pharmacy and Therapeutics Committee
- A licensed physician with expertise in the clinical area associated with the test article.

NOTE: The Physician may ask to be excused from participation as the physician reviewer if there is a perceived conflict of interest.

Life threatening: Any disease or condition where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life threatening do not require the condition to be immediately life threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the CHS CIRB is feasible.

Subsequent Use: Any use of the test article that occurs after its initial emergency use. Any subsequent use of the test article shall require the prior approval of the CHS CIRB in compliance with the Full Review requirements. Should a situation arise which would require the emergency use of the same test article for a second patient, either by the same or second physician, subsequent emergency use will not be withheld for the purpose of gaining CHS CIRB concurrence. **If it appears probable that similar emergencies or requests for treatment will require subsequent use of the test article, every effort should be made by the physician to sign on to the sponsor's protocol or to develop a protocol for future emergency use of the article within the hospital.**

PROCEDURE FOR EMERGENCY USE OF A TEST ARTICLE

Investigator Responsibilities

1. Complete and submit the *Application/Report for the Emergency/Compassionate Use of a Test Article Form* within five (5) working days of use of the test article. This form may be used to either apply for or report the emergency use of a test article.
2. Submit all supporting documentation:
   - Copies of the clinical documentation supporting the need for the emergency use of the test article

Department Responsibilities

1. Review application and supporting documentation. May request further clarification.
2. Forward documentation to Chair, CHS CIRB. Chair may elect to consult with an Independent Physician Reviewer in addition to the one listed on the application/report.
3. Notify Principal Investigator in writing of Chair's concurrence or non-concurrence of the report of use

   NOTE: This notification is an acknowledgement only and should not be construed as approval for the current use or for subsequent use of the test article.

4. The documentation will be reviewed at the next scheduled meeting of the CHS CIRB.

PROCEDURE FOR NON-EMERGENT/COMPASSIONATE (OFF-LABEL) USE OF A TEST ARTICLE

Investigator Responsibilities

1. The investigator will seek approval prior to using the test article for an off label compassionate use.
2. Submit an *Application/Report for the Emergency/Compassionate Use of a Test Article* to the CHS CIRB prior to use. The investigator should be very specific regarding:
   - A description of the patient's condition and the circumstances necessitating treatment,
   - A discussion of why alternative therapies are unsatisfactory, or
   - That no other alternative treatments are available.
   - The independent assessment from an uninvolved physician.
3. If the Investigator received CHS CIRB concurrence for the compassionate use of the test article, prior, written informed consent must be obtained from the patient or their legal representative informing him of the "off- label" use of the test article.

4. The Investigator will submit all documentation to the sponsor of the test article as required by their policies and procedures.
5. The Investigator will submit a "follow-up" letter to the CHS CIRB within 5 working days following use of the test article stating;
    - A summary of the use of the test article, the indication and patient outcome;
    - A summary of any adverse events;
    - The plan for continued monitoring of the patient;
    - Any additional information stipulated by the CHS CIRB upon concurrence,

Department Responsibilities

1. Review application and supporting documentation. May request further clarification.
2. Forward documentation to the Chair, CHS CIRB. Chair may elect to consult with an Independent Physician Reviewer in addition to the one listed on the application.
3. Notify Principal Investigator in writing of the Chair's concurrence or non-concurrence for the compassionate use of the test article.

   NOTE: This notification is an acknowledgement only and should not be construed as approval for subsequent use of the test article.

4. The documentation will be reviewed at the next scheduled meeting of the CHS CIRB.

CROSS REFERENCE
CHS CIRB Policy: Humanitarian Use Device (HUD), Humanitarian Device Exemption (HDE) IRB 13

REFERENCE:
Code of Federal Regulations, 21 CFR 50.23; 21 CFR 56.104

ACCEPTED BY:

Elizabeth Yee
Vice President, Clinical Ancillary Services

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Chair, CHS CIRB

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REVIEWED AND APPROVED BY: CHS CIRB 6/7/05, 2/12/2008, 6/8/2010, 6/2013, 5/10/2016, 6/2020

DATE REVISED: 1/2008, 5/2010, 11/2017

REVIEWED BY:

Date	Initials
5/2010	JL
3/2013	JL
5/2016	JL
11/2017	JL
6/2020	JL