TITLE: Review of a Protocol Involving a Medical Device: Assessing Significant and Non-Significant Risk		POLICY/PROCEDURE NUMBER: IRB 8	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB
SUPERSEDES:	None	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	8/15/06	DATE EFFECTIVE:	3/2020

X	CFNI Munster, Indiana	X	Community Hospital Munster, Indiana	X	St. Catherine Hospital East Chicago, Indiana	X	St. Mary Medical Center Hobart, Indiana

POLICY STATEMENT/PURPOSE: Clinical investigations of medical devices must comply with the Food and Drug Administration (FDA) informed consent and Institutional Review Board (IRB) regulations [21 CFR Parts 50 and 56, respectively] as well as those that regulate the medical devices [21 CFR Part 800 through 1050].

DEFINITIONS: See Addendum II

Significant Risk (SR) verses Non-Significant (NSR) Risk Devices

1. Unless exempt by the IDE regulations, an investigational device must be categorized as either a Significant Risk (SR) device or a Non-Significant Risk (NSR) device. The device sponsor makes the initial risk assessment. The CHS CIRB will make a final determination regarding the appropriate SR/NSR category during a convened meeting.
2. Research involving the use of a SR device must be conducted in accordance within the full requirements of FDA and must have an approved IDE from FDA.
3. Research involving the use of a NSR device must be conducted in accordance with the “abbreviated” requirements of FDA as described in the FDA regulations 21 CFR Sec. 812.2(b).

CHS CIRB Approval of the Use of an Investigational Device

1. Both SR and NSR risk device studies must go to full committee for review and approval. The minutes of the meeting will reflect the CHS CIRB determination and document any related discussion.
2. The CHS CIRB may approve or disapprove the proposed research based on local context and its responsibilities to protect human subjects in research even when FDA has granted approval of the device.
3. The initial submission will include all correspondence from the sponsor and/or FDA to include:
    a. Determination of the device as being a NSR or SR device.
    b. Explanation of a NSR determination and any other information that may assist the CHS CIRB in evaluating the risk of the study.
    c. Description of the device, reports of prior investigations with the device, the proposed investigational plan, a description of patient selection criteria and monitoring procedures, as well as any other information that the CHS CIRB deems necessary to make its decision.
    d. Information whether any other IRBs have reviewed the proposed research and the determination that was made.
    e. The FDA’s assessment of the device’s risk if such an assessment has been made.
4. The CHS CIRB office will review the initial documentation from the investigator using the Risk Determination Form-Devices. This form will be attached to the original forms submitted with the CHS CIRB agenda to assist the CHS CIRB in their review.
5. The CHS CIRB must determine whether it is in agreement with the rendering of the decision by the sponsor of the device being a NSR or SR device.

a. If the CHS CIRB and the sponsor agree that the investigational device is of NSR, the initial review and approval may proceed as for any other FDA regulated study.
b. If the sponsor determines the investigational device to be of a NSR and the CHS CIRB disagrees, the CHS CIRB will notify the investigator, in writing, of its determination.
    - The sponsor or the investigator may proceed with submitting a request for an IDE approval from FDA and re-submit the study for review; or
    - The sponsor or the investigator may withdraw the study and not submit the investigational device to FDA for consideration of an IDE.
c. If FDA rules that the investigational device is a SR device after the sponsor and the CHS CIRB have determined the investigational device to be a NSR device, the CHS CIRB will suspend the currently approved study informing the investigator of the criteria for suspension.
    - The study may not reopen until FDA grants an IDE and the full CHS CIRB reviews and approves all changes.

Exemptions from IDE Requirements
A device can be exempt from the IDE requirements. The sponsor and the investigator must clearly indicate which exemption is being claimed. It is the sponsor's responsibility to provide sufficient justification to support the exemption category being claimed. An exemption from the IDE requirement is not an exemption from the requirement for prospective CHS CIRB review or informed consent.

1. Exemption category under 21 CFR Sec. 812.2(c)(3). In addition to the sponsor's compliance with applicable requirements in 21 CRF Sec. 809.10(c), the device must comply with the following;
    - Is non-invasive;
    - Does not require an invasive sampling procedure that presents significant risk;
    - Does not by design or intention introduce energy into a subject; and
    - Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

2. Exemption category under 21 CFR Sec. 812(c)(4). To qualify for this exemption, the device testing must not be for the purposes of determining safety and effectiveness and must not place subjects at risk.
    - Consumer preference testing;
    - Testing of a modification; or
    - Testing of a combination of two or more devices in commercial distribution.

3. Humanitarian Use Device: See CHS CIRB Policy: Humanitarian Use Device (HUD) Humanitarian Device Exemption (HDE)

4. Emergency Use of a Test Article (Compassionate/Humanitarian Use): See CHS CIRB Policy: Emergency Use of a Test Article (Compassionate/Humanitarian Use) and Application /Report for the Emergency Use of a Test Article

Investigator Responsibilities:
1. Complete and submit all documentation required by the CHS CIRB. (Refer to Submission Form)
2. Ensure that the investigation is conducted according to the CHS contractual agreement with the sponsor, the CHS CIRB approved protocol, and applicable regulations.
3. Comply with all Institutional, State and Federal regulations in regards to distribution of test articles.
4. Provide all information regarding the use of investigational devices as required in the CHS CIRB Submission Form. This will include the identification of the IDE number, if applicable.
5. Ensure accountability, storage, dispensing, tracking, disposition, and oversight of the investigational device.
6. Use the device only as described in the CHS CIRB approved protocol and will discard or ship all unused devices back to the sponsor as specified by the sponsor.
7. Obtain informed consent from the subject or the subject's legally authorized representative prior to use of the device.
8. Notify the CHS CIRB of any changes to the investigational device or protocol and adverse events during the course of the study. In addition, notify the CHS CIRB of study closure.

9. Notify the sponsor of all determinations made by the CHS CIRB.

.

CROSS REFERENCE(S):
CHS CIRB Policy: Submission of Protocol to the CHS CIRB; Initial Review, Continued Review, Prior Review by NCI CIRB IRB 4
Protocol Submission Form
Medical Devices Addendum I
Definitions Addendum 2
Risk Determination – Devices Reviewer Form

REFERENCE(S):
21 CFR Part 50
21 CFR Part 56
21 CFR Part 800 - 1050
Information Sheet Guidance for IRB's, Clinical Investigators, and Sponsors FAQs about Medical Devices
Information Sheet Guidance for IRB's, Clinical Investigators, and Sponsors Significant Risk and Nonsignificant Risk Medical Device Studies
FDA Information Sheets: Medical Devices
FDA Website "Device Advice"
IRB Management and Function; Amdur, R. and Bankert, E.; Second Edition; 2006 Jones and Bartlett Publishers, Inc.

ACCEPTED BY:

Elizabeth Yee
Vice President, Clinical Ancillary Services

Andrej Zajac, M. D.
Chair, CHS CIRB

Jana L. Lacera, RN, MSA, CDM
Human Protections Administrator, CHS CIRB
Director, IRB/Bio-Ethics

DATE(S) REVISED: 11/06, 11/2017

REVIEWED BY: CHS CIRB 9/13/2006, 1/10/07, 5/2010, 6/11/2013, 5/10/2016, 11/2017, 3/2020

Date	Initials
1/2007	JL
5/2010	JL
6/2013	JL
4/2016	JL
11/2017	JL
3/2020	JL