

TITLE: CHS CIRB Fees		POLICY/PROCEDURE NUMBER: IRB 19	
Author:	Jana L. Lacera, RN, MSA, CDM	Applicable To:	CHS CIRB
Supersedes:		Issued By:	CHS CIRB
Date Originated:	2/23/05	Date Effective:	6/2020
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CFNI X Munster, Indiana	X Community Hospital Munster, Indiana	X St. Catherine Hospital East Chicago, Indiana	X St. Mary Medical Center Hobart, Indiana
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POLICY/PROCEDURE STATEMENT/PURPOSE:

In order to underwrite service improvements and educational programs sponsored by the CHS CIRB, the CHS CIRB will charge all commercially sponsored research studies (e.g., where any form of compensation, payments or benefits are provided either by industry or by grants) a fee of \$2,000.00 for initial CHS CIRB review. The CHS CIRB an initial fee of \$2,000.00 and \$500.00, annually thereafter, for continuing review. Fees are not based on the size of the study budget, the number of subjects enrolled, or whether or not the study is initiated, but rather on the department review and preparation to place the study on the agenda. The fees will be charged to all qualifying studies.

Investigators and/or departments are responsible for payment of the CHS CIRB fee if the sponsor does not ultimately reimburse this fee. There are no anticipated exceptions to the applicability of this fee. Nonetheless, there may be situations in which charging a fee for CHRS CIRB review could restrict or preclude valuable research. The CHS CIRB may therefore reduce or waive its fees when that is necessary to allow research to proceed.

DEFINITIONS:

Full Fee: It is assumed that all funded/sponsored research will be subject to the full fee.

Reduced Fee: The CHS CIRB may reduce the fee for funded/sponsored research based upon the following criteria:

1. Research funded by a commercial sponsor:
 - a. The fee may be reduced to not less than \$500 when it is demonstrated that the research will not be allowed to proceed due to the payment of the full fee.
 - b. The request for reduction must be justified by the sponsor through evidence that:
 - The number of anticipated subjects is inadequate to underwrite the full fee.
 - That the treatment is being developed for primarily humanitarian reasons.
 - Other compelling reasons acceptable to the CHS CIRB.
2. Research funded by a non-commercial sponsor:
 - a. The fee may be reduced for non-commercially sponsored research when it is demonstrated that:
 - The research budget is inadequate to underwrite all necessary research expenses.
3. The fee does not apply if the project recovers full indirect costs at the federally negotiated rate.

Fee Waiver: The CHS CIRB may waive the fee for:

1. Unfunded research.
2. Research sponsored/authored by:

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- a. A physician with medical staff privileges within the Community Healthcare System where the proposed research is unfunded.
- b. Humanitarian research in which a sponsor merely provides the experimental therapy or drug
- c. Research sponsored by non-profit organizations.
- d. Students authoring or participating in unfunded research, i.e., doctoral thesis, etc.

Investigator Responsibilities

1. Will request a hard copy from the IRB Office or print a copy of the Invoice for CHS CIRB Fees
2. Will submit the check for the fee with the initial submission of the protocol for CHS CIRB review.
3. If applicable, will submit a letter identifying the maximum amount allowed by the research sponsor and/or a request to waive the fee.

Office Responsibilities

1. Will make the CHS CIRB Fees Invoice available to the Investigator/Clinical Research Coordinator.
2. In the event of a request for a reduced fee or waiver: the office, in consultation with the CHS CIRB Chair, will determine the acceptability of a reduced fee or a waiver prior to review of the protocol. Factors taken into consideration when determining the appropriate fee may include the size of the study, the number of sites involved, the complexity of the initial and continuing review required and other relevant factors.
3. Will enter the receipt of the fee into the CHS CIRB Database.
4. Will place a copy of the check and the invoice in the Fees Binder.
5. Will deliver the check to the Accountant in General Accounting to be deposited into GL Account Department #48100. A copy of the invoice will accompany the check.

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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 REVISED: 8/05, 2/06, 5/2010, 11/2017

REVIEWED BY: Reviewed and accepted by the CHS CIRB 8/9/05, 6/2009, 6/2010, 6/11/2013, 5/10/2016, 11/2017, 6/2020

Date	Initials
6/2009	JL
4/2010	JL
5/2013	JL
4/2016	JL
11/2017	JL
6/2020	JL