TITLE: Request to Close a Research Study		POLICY/PROCEDURE NUMBER: IRB 11	
Author:	Jana L. Lacera, RN, MSA, CDM	Applicable To:	CHS CIRB
Supersedes:	None	Issued By:	CHS CIRB
Date Originated:	2/8/05	Date Effective:	4/2020
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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 require prompt reporting to the IRB of proposed changes in a research activity. The CHS CIRB requires that investigators report when study activities including enrollment, intervention/interactions, and data analysis of identifiable private information or identifiable biospecimens have been completed. Analysis of de-identified research data may continue after study closure.

Investigator Responsibilities

1. Complete and submit a *Request to Close a Research Study form.*
2. Attach any documentation received from the sponsor regarding the closure of the study.
3. If available, attach any other new findings, final reports, publications that relate to the study.

Department Responsibilities

1. Upon receipt of the request to close a study, the documents will be reviewed for completeness. Investigators will be contacted to provide clarification and/or additional documentation if necessary.
2. The request will be placed on the agenda of the next scheduled meeting of the CHS CIRB when all completed documentation has been received.
3. The closure will be entered into the CHS CIRB Database as closed upon the review and approval of the CHS CIRB.
4. The completed study file will be maintained for a minimum of three years from the date of closure.
5. The investigator will be notified in writing of the completed closure of the study following the convened meeting.

ACCEPTED BY:

Elizabeth Yee
Institutional Official, CHS CIRB
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: 2/8/05, 7/2009, 11/2017

REVIEWED BY: CHS CIRB 2/8/05, 6/2009, 9/2009, 4/2013, 3/8/2016, 4/2020

Date	Initials
6/2009	JL
3/2013	JL
2/2016	JL
11/2017	JL
4/2020	JL