

CATHOLIC HEALTH SYSTEM IRB APPLICATION FORM**Site Applicable to:**

- Kenmore Mercy Hospital
 - Mercy Hospital
 - Sisters Hospital-St. Joseph Campus
 - Sisters of Charity Hospital
 - Affiliated Off-sites and/or Long Term Care Facilities of the CHS
- (Specify which sites): _____

Completed by: _____**Phone:** _____**COMPLETE ALL QUESTIONS****1.) Title of Project (as it appears on the Protocol AND Consenting Documents):**

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2.) Type of Project:

New:		
Continuing/Renewal:		CHSIRB # (for continuing studies Ex: SOCH/IRB/0808):

3.) Level of Review Requested:

Full Review:		Expedited Review:		Exempt Review:	
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4.) Principal Investigator:

PI Name (first/last/degree):			
PI Complete Mailing Address:		Department:	
		Hospital:	
		Address	
City:		State:	Zip:
PI Phone Number:	Ext:	PI Fax Number:	
PI Email Address:			

5.) Check where study documents and notifications should be sent:

To the PI at this address:		To the Administrative contact person in #7 below		Both:	
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6.) Advisor (for students and residents):

Advisor (first/last/degree):
Advisor Email Address:

7.) Administrative Contact (Study Coordinator/Administrator):

Administrative Contact Name (first/last/degree):			
Administrative Contact's Complete Mailing Address:		Department:	
		Hospital:	
		Address:	
		City:	State:
Admin Contact Phone Number:	Ext:	Admin Contact Fax Number:	
Admin Contact Email Address:			

8.) Sites where research will be conducted.							
A. Check all Catholic Health System Sites that will apply:	SOCH		MHB		SJH		KMH
B. Indicate all CHS affiliated Home Care Sites that apply: (e.g., McCauly Seton)							
B. Indicate all other local sites: (e.g., ECMC, Millard Gates etc.)							
C. Indicate all other sites within the USA (e.g., University of Rochester)							
D. Indicate countries outside the USA:							

9.) Source of Support: Complete either A, B or C (Please note: If your research is commercially sponsored or grant supported, it must go through a complete financial analysis prior to being placed on the CHS IRB Agenda. Refer to the CHS IRB Website for further instructions)		
A. External Sponsored Research:	YES / NO	
Sponsor and Sponsor Address:		
B. Internally Supported Research:	YES / NO	
Source of Support and Address:		
C. Unfunded Research:	YES / NO	
If YES, Indicate source of support for this study (e.g., self, department funds, etc.):		

10.) Repository of Research Files: Indicate location (i.e., the complete address including campus or hospital, dept, and room #,) where human subjects documentation (e.g., consent forms, IRB documents, etc.) will be retained during the study:			
Complete Repository Address:	Department:		
	Address:		
	Room #:		
	City:	State:	Zip:

11.) Education Requirements: The Catholic Health System IRB Policy requires all research personnel involved in human research projects to meet initial and continuing education requirements in the protection of human research subjects. Before a new project is reviewed and approved by the CHS IRB, all research investigators and staff must demonstrate that they have successfully met the education requirements. Currently, they must read and document an understanding of the Belmont Report. It is necessary to submit a copy of the signed "Belmont Report Statement" along with the complete submission of IRB requirements for review.

Research staff = PIs, Co-PIs, all individuals who will obtain consent, study/research coordinators, study/research managers, data collectors, recruiters, interviewers, and statisticians.

11.a. List all research staff who will be working in the following capacities and indicate their specific role(s) on the research project: PIs, Co-PIs, ALL individuals who will obtain consent, study/research coordinators, study/research managers, data collectors, recruiters, interviewers, and statisticians. **Individuals obtaining consent MUST be identified.**

Name (please print) First/Last	E-mail	Indicate Specific Role(s)/Responsibilities on Research Project
<i>Example: Dr. Stetha Scope</i>	<i>stetha@scopej.org</i>	<i>Obtain consent, interview, data entry</i>

12.) Financial Disclosure Requirements (For Sponsored Research Only): The CHS policy requires that all CHS investigators and co-investigators of sponsored research projects complete an *Annual Conflict of Interest Statement* annually and file it with the CHS IRB office. The form can be found at www.CHSBuffalo.org/education/IRB.

12.a. Annual Disclosure Statement on file with CHSIRB Office: My signature below confirms that I have a current *Annual Conflict of Interest Statement* on file with the CHS IRB Office. **This form must be on file or approval/re-approval will be delayed. Updated disclosure forms must be re-filed annually in accordance with the review and approval of your study.**

Names of Investigators and Co-Investigators (please print)	Location of CHS IRB office where <i>Conflict of Interest Statement</i> will be kept

12.b. Are there any Co-PIs on the research project who are NOT affiliated with CHS?	YES / NO
If NO, skip to #13.	
If YES, provide the following information regarding the Non-affiliated Co-PI:	
• Name of the Co-PI	
• Does the Co-PI have a Significant Financial Interest?	YES / NO
• Where is the documentation regarding the determination of Significant Financial Interest retained?	
• If a significant Conflict of Interest has been identified, has it been satisfactorily addressed? Explain.	

