



Policy Number	Policy Title	Effective Date
2274.3	Institutional Review Boards Policy	Nov 4, 2011
Policy Type	Area	Applies To
Research		System

POLICY

Any research conducted in a Norton Healthcare facility will have approval from the University of Louisville Human Subjects Protection Program Institutional Review Board, the Western Institutional Review Board (WIRB), or for student research an institution with which Norton Healthcare has an IRB Authorization Agreement (IAA). The investigator will follow the rules and regulations set forth by the respective IRB (i.e., annual review, amendments, informed consent) or he/she cannot conduct research in a Norton Healthcare facility. Those researchers affiliated with the University of Louisville or utilizing a University of Louisville facility for research must use the U of L IRB as the IRB of record. Those not affiliated with the University of Louisville may use the U of L IRB, WIRB, or the IRB identified in an IAA as the IRB of record.

For all research intended to be conducted at a NHC facility in which the University of Louisville Institutional Review Board is the IRB of record, an electronic application must be submitted to U of L IRB through the BRAAN2 (electronic) system. Instructions for using BRAAN2 may be found on the IRB's website, <http://louisville.edu/research/humansubjects>. If a NHC facility is selected as a research site on the application, the NHORA will have access to all documents in the system associated with the research study. Please direct all BRAAN2 questions to the HSPPO at 502-852-5188.

For all research intended to be conducted in a NHC facility in which the Western IRB (WIRB) is the IRB of record, the application must be submitted to NHORA for conditional approval prior to submission to WIRB. The WIRB submission materials are available on their website, www.wirb.com. WIRB will not accept a NHC application without the NHORA conditional approval letter.

Please refer to the Research Submission Policy or SOPs for Conducting Research at Norton Healthcare for full instructions on the IRB submission, review and approval process.

Replaces Policy Dated:		Reviewed/Approved by: (Group or Individual)
Review	Revision	
12/31/02		Effective
	12/31/03	Norton Healthcare Research Office
	10/01/04	Norton Healthcare Research Office
	06/30/05	Norton Healthcare Research Office
	6/12/06	NHRO, Legal
	11/4/11	NHORA

The policies and procedures set forth in this policy library do not establish a standard to be followed in every case. It is impossible to anticipate all possible situations that may exist and to prepare policies for each. These policies should be considered guidelines with the understanding that departures from them may be required at times. Accordingly, it is recognized that those individuals employed in providing healthcare are expected to use their own judgment in determining what is in the best interests of the patient based on the circumstances existing at the time. If this policy contains reference to clinical literature, the literature cited is only intended to support the reasoning for adoption of certain guidelines contained herein. It is not an endorsement of any article or text as authoritative. Norton Healthcare specifically recognizes there may be articles or texts containing other opinions on point that may be helpful and valid which would support other care or actions, given a particular set of circumstances. No literature is ever intended to replace the education, training and experience or exercise of judgment of the healthcare providers.

Revision	Approval Date	Reviewed / Approved By: (Group or Individual)
2274.3	Nov 04, 2011	Rhonda Hoffman