



Policy Number	Policy Title	Effective Date
4155.2	Regulatory Maintenance of Research Conducted at Norton Healthcare	Nov 4, 2011
Policy Type	Area	Applies To
Research		System

POLICY

Any investigator conducting research in a Norton Healthcare facility, after having obtained NHORA approval, will be responsible for ensuring that the NHORA receives the appropriate research documentation during the course of the research project.

PROCEDURE

- The following documentation is required to be submitted to the NHORA as appropriate
 - Annual progress report/continuation review form
 - Annual approval letters and current informed consent forms approved by the IRB, if applicable
 - Amendments and amendment approval letters pertaining to changes in personnel, accrual goals, treatment plan, safety, or sponsor status.
 - Revised HIPAA documents (e.g. revised partial or complete waivers)
 - Conflict of interest disclosure for new personnel, or changes in the conflict of interest status for present personnel
 - Status change of the study (e.g. closed to enrollment, study termination)
 - Changes in the budget, contracts or grants
- The documentation may be emailed to the NHORA at NHORA@nortonhealthcare.org, or faxed to (502) 456-7199.
- The NHORA may be copied on IRB email correspondence containing the above documentation. However, it is the investigator's responsibility to ensure that the NHORA receives the documents.

Replaces Policy Dated:		New
Review	Revision	Reviewed/Approved by: (Group or Individual)
6/12/06		NHRO, Legal Department
	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)
4155.2	Nov 04, 2011	Rhonda Hoffman