



Policy Number	Policy Title	Effective Date
6685.1	Norton Healthcare Office of Research Administration - Vision & Mission	Nov 4, 2011
Policy Type	Area	Applies To
Research		System

POLICY

Vision

- To assist Norton Healthcare in becoming a recognized leader in the conduct of clinical research

Mission

- To increase the depth and breadth of studies conducted at Norton Healthcare
- To assist investigators in the conduct of research in a customer service oriented and ethical manner
- To represent the mission and vision of Norton Healthcare and to uphold regulatory and compliance principles for the proper conduct of research within our facilities

NHORA is responsible for the oversight of all clinical research activities within Norton Healthcare (NHC). Such activities include:

Compliance/Regulatory:

- Compliance/Regulatory review of every study submitted to Norton Healthcare
- HIPAA compliance
- Regulatory submission to the Institutional Review Board (IRB) for Norton employed groups and continued regulatory oversight for life of the study
- Liaison with the University of Louisville Institutional Review Board and Western Institutional Review Board
- Perform compliance audits of research studies performed within a NHC facility
- Maintain Norton Healthcare's HHS Federalwide Assurances (FWA)
- Serve as Liaison with federal and state agencies

Finance:

- Financial review of every study submitted to NHORA
- Contract and budgeting
- Financial management of research revenues and expenses
- Management of research billing/claims for research subjects treated in NHC facilities
- Responsible for the annual budget process for all research groups at NHC
- Study Manager/Reveal Administrator for NHC

Education:

- Gaining Essential About Research (GEAR) program development and administration

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)
6685.1	Nov 04, 2011	Rhonda Hoffman