NORTON HEALTHCARE

Policy Number	Policy Title	Effective Date
2277.4	Research Submission Policy	Nov 4, 2011

Policy Type	Area	Applies To
Research		System

POLICY

Any researcher conducting research in a Norton Healthcare, Inc. facility must first receive approval from the Norton Healthcare Office of Research Administration (NHORA) and an institutional review board (IRB). Norton Healthcare holds a Federal-Wide Assurance with the Office for Human Research Protections listing the University of Louisville IRB and the Western IRB (WIRB) as IRBs of record for this institution.

PROCEDURE

The following documents are required in your submission to NHORA (as appropriate to type of study):

- JHSMH/NHC MIRA form (if study performed at multiple institutions)
- Completed IRB application (WIRB only)
- Scientific and Scholarly Merit Review Form (U of L only)
- Informed Consent Form (ICF) using the approved language template OR an application of a waiver of informed consent
- Applicable HIPAA documents (e.g. Research Authorization, Complete or Partial Waiver)
- Protocol and Synopsis
- Time & Events schedule delineating research v. conventional procedures, signed and dated by PI which will be used to create the Billing Compliance Table (BCT)
- Recruitment Advertisements
- FDA Form 1572, if applicable
- Contract or Letter of Agreement (draft is acceptable until finalized)
- Budget (draft is acceptable until finalized)
- CV (Curriculum Vitae) and current professional license for the PI and Sub-Is
- Certification of Human Subjects Protection Training (CITI) for key personnel
- For drug studies: Investigational Drug Brochure or background information for food supplements
- Gene Therapy protocols: either a request for Institutional BioSafety Committee (IBC) review or the IBC approval
- For device studies: a copy of the signed investigator agreement for protocols with an IDE and **one** of the following:

    - FDA letter approving the Investigational Device Exemption (IDE)
    - 510(k) clearance
    - Letter from the sponsor stating significant or non-significant risk (final designation determined by the IRB)
    - Pre-Market Approval (PMA) letter
    - PMA supplemental letter
    - PMA amendment letter

Submission Process Using the University of Louisville Institutional Review Board

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 UofL 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 studies, excluding chart reviews, a BCT will be completed by the PI. The PI must designate each procedure on the protocol "schedule of events" as either "C" for conventional, or "R" for research billing. A procedure classified as conventional is one that would be performed in the patient population at the protocol-required time point outside of clinical trial participation. The PI and person completing the form must sign and date the schedule, and send to the NHORA.

Once the above-listed documents are available as a complete package, the study is assigned a NHORA tracking number. The NHORA tracking number is sent to the researcher along with confirmation of receipt of submission. This number should be used in all correspondence relating to the study.

The NHORA will conduct an internal evaluation of the submission to include regulatory, compliance and financial review. Any questions or comments raised during the review will be forwarded to the researcher within 5 business days. If a response is not received in 10 business days, the researcher will be queried.

Final NHORA approval will be granted upon receipt of resolved questions/issues, IRB approval, department approval and final contrac

Scientific or Scholarly Merit Reviews

The University of Louisville requires a Scientific or Scholarly Merit review of every research study involving human subjects proposed to take place in NHC facilities where the University of Louisville is the IRB of record. The purpose of this review is to ensure that the scientific approach is sound, that the research design will yield valid results and appropriate departmental resources are approved and available for the completion of the project. Each NHC employed researcher is responsible for identifying one or more impartial and competent peers to assess the project for scientific or scholarly merit.

The review takes place according to the following procedure:

- The Investigator identifies the scientific and scholarly merit reviewer(s) and provides the reviewer with a copy of the research documents.
- The reviewer assesses the research for scientific or scholarly merit, completes the NHC Scientific or Scholarly Merit Review of Research Protocols Involving Human Subjects form and returns the signed document to the Investigator.
- The Investigator, or NHORA personnel, uploads the NHC Scientific or Scholarly Merit Review of Research Protocols Involving Human Subjects form as part of the BRAAN2 submission.
- Once submitted in BRAAN2 the Systems Director of NHORA will sign off as the Institutional Official on the IRB submission to complete the process.

Submission Process Using the Western Institutional Review Board

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.

Once the above-listed documents are available as a complete package, the study is assigned a NHORA tracking number. The NHORA tracking number is sent to the researcher along with confirmation of receipt of submission. This number should be used in all correspondence relating to the study.

The NHORA will conduct an internal evaluation of the submission to include regulatory, compliance and financial review. Any questions or comments raised during the review will be forwarded to the researcher

within 5 business days. If a response is not received in 10 business days, the researcher will be queried.

Once all questions and comments have been addressed, NHORA will issue the NHORA Conditional Approval Letter to the researcher. WIRB will not review a study submission with NHC as a facility without the NHORA Conditional Approval letter.

Researcher will submit WIRB application and study documents, along with NHORA Conditional Approval Letter using the WIRB online submission website.

Final NHORA approval will be granted upon receipt of resolved questions/issues, IRB approval, department approval and final contract

For all studies, excluding chart reviews, a BCT will be completed by the PI. The PI must designate each procedure on the protocol "schedule of events" as either "C" for conventional, or "R" for research billing. A procedure classified as conventional is one that would be performed in the patient population at the protocol-required time point outside of clinical trial participation. The PI as well as the person completing the form must sign and date the schedule, and send to the NHORA.

Replaces Policy Dated:		
Review	**Revision**	**Reviewed/Approved by: (Group or Individual)**
12/31/02		Effective
	12/31/03	Norton Healthcare Research Office
	5/12/05	Norton Healthcare Research Office
	06/12/06	Norton Healthcare Research Office
	12/20/07	Norton Healthcare Research Office
	11/4/2011	Norton Healthcare Office of Research Administration

Revision	Approval Date	Reviewed / Approved By: (Group or Individual)
2277.4	Nov 04, 2011	Rhonda Hoffman