NORTON HEALTHCARE

Policy Number	Policy Title	Effective Date
3520.3	Informed Consent Process - Research	Nov 4, 2011

Policy Type	Area	Applies To
Research		System

POLICY

Unless a waiver is granted by the IRB of record, the Principal Investigator is responsible for ensuring that, prior to any study activity, each subject participating in research in a NHC facility signs an Informed Consent Form (ICF) that is approved for use by both the IRB and NHORA. The ICF must be obtained in accordance with this policy, applicable law and regulations and be kept in the official NHC medical record. The consent process must be clearly documented and contain the components set forth in CFR 50, Subpart B and Subpart D.

PROCEDURE

1. Prior to beginning a study involving human subjects, it is essential to obtain the informed consent of the person or his/her authorized representative. Informed consent is an expression of the willingness of a person to participate as a subject in research. To be effective, the consent must be freely given, without coercion, and must be based on a clear understanding of the nature and purpose of the study and what will be required of the subject to participate.

The discussion with the potential participant by the researcher should include the purpose of the research, the procedures to follow, and all known discomforts, risks, benefits (both short and long-term), any costs to the subject, Conflict of Interest information, and release of information for billing compliance. The signing of the consent document should signify that thorough discussion has taken place and will continue to take place during the conduct of the study. Informed consent is an ongoing process throughout the subject's participation in the study.

Subjects being asked to participate in diagnostic or therapeutic studies should be informed of alternative choices for diagnosis or treatment. All subjects should know if their treatment is to be determined by random selection and if placebos are to be used. No information should be withheld that might influence the subject's decision; nor should there be promise of beneficial results. The subject should feel at liberty to refuse to take part in the study, or to discontinue participation at any time, without prejudice to present or future care.

2. The same principles that pertain to obtaining informed consent from subjects should also be applied by researchers in making a request for consent from parents, next-of-kin, or Legally Authorized Representatives (LAR) of those persons unable to give informed consent due to minor age, physical incapacity or cognitive impairment. In such cases, a special request to include these individuals in the research must be made and the IRB of record will determine if a LAR is permitted. The LAR is expected to act in the best interests of the subject by sharing in discussions with the researcher and with those responsible for giving consent. Although minors are unable to give informed consent for themselves, children of seven (7) years or older should participate in the consent process by providing their assent to join the study when appropriate.

3. An individual's willingness to take part in a study must be documented by the written consent form, as determined by the IRB of record, or if approved by the IRB, by oral consent and noted in the subject's medical record.

4. There must be no coercion and care must be exercised to avoid any appearance of coercion used to induce subjects to take part in or remain in a study. This is especially important if the subject is in a dependent relationship to the researcher or if monetary rewards are offered for participation. Potential subjects must be allotted a reasonable amount of time to consider participation.

5. Non-English speaking subjects must be given a certified translated Informed Consent Form that is approved by the IRB of record. In order to ensure that the person explaining the study is a certified translator, only NHC-approved certified translators may be used. If the translator is the sole person obtaining consent and interacting with the subject at research visits (as the only research staff member who speaks their language), the translator must be approved by the IRB as key research personnel.

6. Illiterate English speaking subjects can "make their mark" on the Informed Consent document, as long as it is consistent with applicable state laws and not prohibited by the IRB.

7. Under very specific circumstances, the IRB of record may waive the requirements of the Informed Consent. (DHHS 45 CFR 616.116)

8. The original subject informed consent, HIPAA authorization, and assent form (if applicable) shall be retained in the investigator's research files, and a copy shall be given to the research subject. A copy of these documents will be filed in the subject medical record at the time of consent. An investigator will have two (2) weeks from the time of consent to sign these documents.

Because of this two-week grace period, NHC accepts the filing of the informed consent documentation in the medical record without the investigator's signature, but the form must contain the signatures of the subject and the person obtaining consent.

Replaces Policy Dated:		
Review	**Revision**	**Reviewed/Approved by: (Group or Individual)**
12/31/02		Effective
	12/31/03	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)
3520.3	Nov 04, 2011	Rhonda Hoffman