



Policy Number	Policy Title	Effective Date
4156.4	Credentialing Requirements for Human Subjects Research	Nov 4, 2011
Policy Type	Area	Applies To
Research		System

**POLICY:** This policy is applicable to non-Norton Healthcare (NHC) employed research personnel having contact with patients or protected health information (PHI) in any NHC facility. All research personnel having contact with patients or PHI within NHC must meet applicable credentialing requirements before conducting research within NHC. All research subjects seen in NHC facilities are considered NHC patients and therefore all NHC policies apply. Credentialing is the initial step in conducting research with human subjects at NHC.

**Non-Compliance with NHC Research Policies:** Breaches of NHC Research policies may result in NHORA termination of the study, exclusion of NHC data collected as part of the research project, and notification of the breach to the IRB of record.

**Human Subjects: Federal Policy definition 45 CFR 46.101 (a):** Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

**Key Research Personnel Definition:** Key research personnel are defined as the Principal Investigator (PI), Co-PI, Sub-investigator(s), Study Coordinators and all other personnel, including students who are in contact with research subjects or their PHI.

**Credentialing for all non-NHC employed research personnel: Level I**

There are two classes of Level I credentials. Both classes are processed internally through the Norton Healthcare Office of Research Administration (NHORANHORA), and do not require dependent allied health privileges (DAHP).

**No Patient Contact**

Those granted credentials under this classification are limited to PHI access only, such as chart reviews and case studies.

**Limited Patient Contact**

Those granted credentials under this classification have access to PHI as well as limited patient contact under the supervision of a privileged medical staff member at NHC. This limited contact may include recruiting subjects, conducting the informed consent discussion, administering questionnaires and surveys, collecting existing data, and other limited research activities. This also includes non-invasive medical procedures such as taking vital signs. Such non-invasive medical procedures performed by a researcher with Limited Patient Contact privileges are not a substitute for those performed by NHC clinical staff in accordance with applicable assessment/reassessment policies.

**Credentialing for all non-NHC employed research personnel: Level II**

Level II credentials allow for all privileges classified as Level I as well as expanded patient interaction under the supervision of a privileged medical staff member at NHC. This includes all patient discussions, procuring specimens, providing appropriate clinical care, performing applicable tests or procedures, and operating equipment (that directly impacts patients) within the scope of their licensing. Sponsoring physicians should be listed as Key Personnel with the IRB for each study in which NHC will be used as a research site.

**Credentialing For Norton Healthcare Employees:** Norton Healthcare employees must operate within the scope

and licensing of their position. When a NHC employee engages in research as Key Research Personnel, they must complete the NHORA Annual Financial Disclosure Form and requirements set forth by the IRB of record.

### **Credentialing for Students:**

- Students who are associated with programs, schools or institutions with a current clinical affiliation agreement in place with NHC will not require any additional credentialing to participate in research, as long as they are in compliance with, and operate within the scope of the agreement.
- Students who are associated with programs, schools or institutions that do not have a current affiliation agreement in place will require credentialing based on the proposed research activity to take place in NHC facilities.

### **Nursing Faculty**

- All nursing faculty with an academic appointment in an institution or department with a current clinical affiliation agreement in place with NHC will not require any additional credentialing to participate in research, as long as they are in compliance with and operate within the scope of the agreement. Verification of completion of the nurse applicant's own institutional credentialing process should be available upon request.
- Nursing faculty associated with institutions or departments that do not have a current affiliation agreement in place will require credentialing based on the proposed research activity. A NHORA Financial Disclosure Form must still be submitted annually.

### **Procedures for Level I Credentialing:**

#### **No Patient Contact**

Research personnel must sign the NHORA Level I application the NHORA, or complete the NHORA Credentialing Certification form, and submit the following documentation:

- Government-issued photo ID
- Documentation of school affiliation (if applicable)
- IS security request form for access to NHC systems (if applicable)
- TB test result within the past year

#### **Limited Patient Contact**

Research personnel must sign the NHORA Level I application in the NHORA, and submit the following documentation:

- Sponsor Certification Form signed by the clinical sponsor, the research supervisor, and the VP or Dean of applicable school
- All documentation required for the "No Patient Contact" access as listed above
- Current proof of professional liability insurance, or other insurance provided by employer, which covers the personnel in performing the research services in NHC facilities with minimum limits in the amount of \$1,000,000 per occurrence, and \$3,000,000 aggregate.
- Documentation of criminal background check performed within six months
- Current signed Curriculum Vitae or resume
- Documentation of immunizations. If no documentation is available, applicant must be immunized at the applicant's or employer's own expense:

-Measles, Mumps, Rubella (MMR)

-Varicella

Upon receipt of the above listed documentation, the NHORA will issue a letter granting research privileges for a pre-determined amount of time. No fee charged for Level I Credentials.

**Procedures for Level II Dependent Allied Health Privileges:**

Applicants for Dependent Allied Health Privileges (DAHP), initial and reappointment, are processed through Norton Healthcare's CVO, the Greater Louisville Medical Society (GLMS) – Centralized Application Processing Service (CAPS). Applicants must first contact the Greater Louisville Medical Society for initial processing. In addition to the documents and fee that will be required by the CAPS office, the following items are required by the System Medical Staff Office of Norton Healthcare:

**Initial Applications**

- \$60 check made payable to Norton Healthcare
- Consent and Release form
- Current proof of professional liability insurance, or other insurance provided by employer, which covers the personnel in performing the research services in NHC facilities with minimum limits in the amount of \$1,000,000 per occurrence, and \$3,000,000 aggregate.
- Background check authorization
- TB test result within the past year
- Proof of a negative drug screen performed by a designated NHC Immediate Care Center
- Documentation of immunizations. If no documentation is available, applicant must be immunized at the applicant's or employer's own expense:

-Measles, Mumps, Rubella (MMR)

-Varicella

- Code of conduct agreement

**Reappointment Applications**

- \$40 check made payable to Norton Healthcare
- Consent and Release form
- Current proof of professional liability insurance, or other insurance provided by employer, which covers the personnel in performing the research services in NHC facilities with minimum limits in the amount of \$1,000,000 per occurrence, and \$3,000,000 aggregate.
- Background check authorization
- TB test result within the past year

**Contacts:**

Norton Healthcare Office of Research Administration	629-3501
System Medical Staff Office	629-4411
IS Security Access Office	629-7976

<b>Replaces Policy Dated:</b> 06/15/06		<b>REVISED</b>
		<b>Reviewed/Approved by: (Group or Individual)</b>
<b>Review</b>	<b>Revision</b>	
6/12/06	08/16/06, 2/15/07, 9/25/07	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)
4156.4	Nov 04, 2011	Rhonda Hoffman