



| Policy Number | Policy Title | Effective Date |
|---------------|-------------------------------|----------------|
| 2279.4 | Compliance Evaluation Program | Nov 4, 2011 |
| Policy Type | Area | Applies To |
| Research | | System |

POLICY

The Compliance Evaluation Program was developed in order to ensure that researchers are adhering to the medical research policies. Compliance evaluations will be initiated under the following circumstances:

1. Not-for-Cause: part of a random selection of studies and programs for review by the NHORA
2. For-Cause: review, when an occurrence of non-compliance is identified or reported.

Any researcher conducting research within a NHC facility is obligated to allow the NHORA to evaluate his/her compliance. Failure to comply with research policies will result in corrective or disciplinary action.

The evaluations will focus on compliance to NHC policies and adherence to human subject protection regulations for all those subjects enrolled in a NHC facility.

PROCEDURE

1. NHORA will notify researchers via email that their study has been selected for review. This notice will be given two weeks prior to the evaluation.
2. The evaluation will verify that the research being conducted is in compliance with NHC research policies. The evaluation may take one to two days depending on the study or program. The compliance evaluator will review all regulatory information for the study, as well as subject information (or a sample) for those subjects enrolled in the study from NHC.
3. A preliminary written evaluation will be sent to the researcher within fifteen business days of completion of the compliance evaluation to allow the researcher to identify and correct any factual errors.
4. A final report will be sent to the researcher within seven business days of receipt of response.
5. The researcher will provide a written response to the final evaluation report within a specified time frame, if any deficiencies are noted.
6. The evaluation report, along with the researcher's response letter, may be sent to the PI, NHORA System Research Director and Compliance Director, the IRB of record, the NHC Corporate Compliance Office, VP of Clinical Research, and the System SVP, Chief Medical Officer of NHC.
7. If necessary, disciplinary guidelines will be addressed based on the findings of the evaluation. Disciplinary actions, if necessary, will be addressed in relation to the severity of any findings of non-compliance. There are three levels of response by the NHORA.
 - If non-compliance is identified, the researcher must provide the NHORA with a Corrective Action Plan with the response letter. The IRB may take separate action.
 - If the researcher does not respond to concerns, or is consistently non-compliant, all research conducted by that researcher will be suspended at NHC and the IRB of record will be notified.

- If the research activity continues after suspension, the NHC System SVP, Chief Medical Officer will send written notification of the breach of NHC policy to the IRB of record, and the Credentials Committee of the Norton facility at which the researcher has primary privileges. In addition, notification will indicate that the researcher's authority to conduct research within NHC has been withdrawn as a result of this breach of policy. Notification may also be provided to OHRP and/or the FDA as appropriate.

| Replaces Policy Dated: | | |
|------------------------|----------|---|
| Review | Revision | Reviewed/Approved by: (Group or Individual) |
| 3/31/04 | | NHRO, Legal |
| 12/11/07 | 12/11/07 | Corporate Compliance |
| | 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) |
|----------|---------------|---|
| 2279.4 | Nov 04, 2011 | Rhonda Hoffman |