

**Northwest Community Hospital  
Institutional Review Board  
General Information on HIPAA**

(ATTACHMENT I – Policy 142)

**TO:** Northwest Community Hospital Researchers

**FROM:** Northwest Community Hospital Institutional Review Board

**RE:** Federal Requirements for Access to Subject Private Healthcare Information (PHI Under HIPAA)

**DATE:** November 28, 2007

**Authorization:**

Under federal law, all subjects enrolled in research on or after April 14, 2003 and subjects re-consenting to participate because of some protocol change must explicitly authorize investigators to have access to their private health information ("PHI") and to use the same. To facilitate compliance with this HIPAA requirement, the Northwest Community Hospital Institutional Review Board (IRB) has developed a template that you must use with your research subjects. This form must be submitted to the IRB for review and approval after you have completed the study specific information required on page one of the template. The IRB does not accept sponsor provided authorization forms and the document may not be incorporated into the informed consent document. If access to PHI is not needed for the study, you do not need to obtain this authorization.

The investigator must give a completed copy of the authorization to the subject and keep each subject's authorization on file.

**Waiver of PHI Authorization Requirement**

Under limited circumstances the IRB may waive the authorization requirement. This may be done in situations where access to and use of PHI is necessary to prepare a research protocol (the PHI is not to be removed from the premises and the PHI must be necessary for research purposes), if the information is already "de-identified" so as to be a limited data set as defined by HIPAA, or for research on decedent's information. A form requesting a waiver is available from the IRB. If the waiver is approved, a copy of the signed approval should be placed in any medical chart from which PHI was accessed.

To obtain these forms, or with questions, please contact the Office of Research at Northwest Community Hospital at 847-618-7970, email at [greiding@nch.org](mailto:greiding@nch.org) or FAX to 847-618-7969.