



**POLICY STATEMENT REGARDING
THE IRB APPROVAL STAMP ON CONSENT FORMS**

8/12/2008

The Duke University Health System Institutional Review Board (DUHS IRB) has determined that study subjects will review and sign a consent form that does not bear an IRB approval stamp and/or statement. It is the DUHS IRB's opinion that a visible IRB approval stamp on a consent form could be interpreted by the potential subject as an endorsement of the study by the DUHS IRB, and could thus unduly influence the subject in making an informed, objective decision regarding his/her participation in the study.

With the advent of the IRB's electronic submission system (e-IRB), the footer on the bottom of each page of the consent form serves as the IRB approval stamp or watermark. The footer is automatically generated by the e-IRB system when a Board Specialist or Medical Writer issues the command to stamp/watermark the consent form as the approved version. The footer contains the following information:

Protocol ID: «**IRBNo**»
Continuing Review Before: «**ExpireDate**»
Reference Date: «**Version**»

The last item in the footer, Reference Date (Version) is the date on which the Board Specialist or Medical Writer issues the command to stamp/watermark the approved consent form. The consent form bearing that Reference Date (Version) in the e-IRB-generated footer is considered the IRB-approved version.