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DATE: March 2, 2011  
TO: University Researchers and Sponsors  
FROM: Daniel K. Nelson, Director  
RE: Signatures on IRB Approval Documents

With our conversion to an electronic environment for submission and review of research applications by the Institutional Review Boards (IRBs), we are also revising our procedures for documenting IRB approvals. Effective immediately, there will no longer be signatures on IRB approval memos.

There is no regulatory requirement that IRB approval documents be signed, and UNC-Chapel Hill policy does not require signatures on such documents. Approval documents are generated electronically by a password-protected IRB information system, with access limited to authorized IRB personnel. Internal tracking and audit procedures are used to verify that only those authorized personnel generate approval documents.

This policy has been adopted by many university IRBs and is supported by guidance from federal regulatory agencies. For example, the FDA does not require IRB chairs to sign or otherwise specify the procedures that IRBs must use for approval letters, only that IRBs should outline the procedures to be followed.

Please feel free to share this explanation with sponsors or others who may question the absence of signatures.