

Date: May 24, 2012
From: Associate Chief of Staff Research (151)
Subj: Addendum to R&D SOP 151-02 (version 3/12/2012)
To: Research Investigators
Thru: ACOS Research (151)

Based on recent guidance from the Office of Research and Development it has been determined that neither the Common Rule (38 CFR Part 16) nor VHA Handbook 1200.05 requires that expiration dates be listed or IRB Chair initial on approved informed consent forms.

After assessing the current procedures it is determined that continuation of this practice does not enhance protections of human subject participants. It is also recognized that discontinuing this practice does not place participants at increased risk.

Effective immediately the requirement in Research and Development Policy 151-02 to add an expiration date to IRB approval stamps as well as the IRB Chair initials is rescinded.

Investigators are advised to continue to use their current IRB Approved consent documents. As these consents are reviewed by the IRB due to Amendment or Continuing Review this will be implemented through the HRPP Office.

Thank you,



MARK POLHEMUS, MD, FACP
Associate Chief of Staff Research and Development

References:

VHA Handbook 1200.05 §33
VA ORD FAQ (ORD: Original Post Date: March 12, 2012, Updated April 16, 2012)