OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION

FAQ Topic: Informed Consent Forms- Implementation of IRB-Approved Revisions to Protocols and Consent Forms

Date: March 12, 2012

Question: How soon after IRB approval must a protocol or informed consent revision be carried out by the research team?

Answer: Although changes in approved research require IRB approval, neither the Common Rule (38 CFR Part 16) nor VHA Handbook 1200.05 specifically stipulates how quickly an IRB must communicate its approval of changes to the investigator or how quickly the investigator must carry out the approved changes. The safety of the research subjects should be of primary concern in this regard. Safety concerns related to the timely implementation of IRB-approved changes should be brought to the attention of the IRB. Where warranted to ensure subject safety, IRBs may stipulate that the approved changes must be implemented prior to the enrollment of new subjects and/or that previously enrolled subjects must be informed of the changes. In such circumstances, the IRB has an obligation to provide the investigator with timely notification sufficient to address the safety issues involved.

Question: Must the revised informed consent form be employed at the same time by all sites involved in a multi-site research project?

Answer: No. If multiple IRBs are involved, it is unlikely that they will all approve the document at the same time. Even if a single IRB (e.g., the VA Central IRB) is involved, release of approval letters for dozens of sites at the same time may not be practical because the forms may need to be individualized for the specific sites. (Original Post Date: March 12, 2012)

References: *38 CFR 16.109(a) and 16.116(b)(5)*
VHA Handbook 1200.05 §14.e
VHA Handbook 1058.01 §7.d and §7.i