OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION

FAQ Topic: HIPAA- Standalone HIPAA Authorizations

Date: March 12, 2012

Question: Must all VA research approved by an IRB after March 31, 2011, and involving the use and disclosure of protected health information (PHI) have a HIPAA authorization that is separate from the informed consent form (unless the authorization is formally waived by the IRB)?

Answer: HIPAA authorizations and informed consent forms must now be separate documents for all VA research initially approved by an IRB after March 31, 2011

Question: When a VA study approved before March 31, 2011, is amended or comes up for continuing review, must the HIPAA authorization be separated from the informed consent form if the forms were previously combined?

Answer: No. The VHA Handbook 1200.05 requirement that the informed consent form and the HIPAA authorization be two separate documents is only applicable to protocols undergoing initial review (whether by full board review or by expedited procedures) after March 31, 2011. This requirement does not apply to amendments or continuing reviews of projects that were initially approved by the IRB on or before March 31, 2011.

References: *VHA Handbook 1200.05 §37.a(2)*