

IRBNews

Office for the Protection of Human Research Subjects

November 2015

For VA Only

The revised VHA Handbook 1200.05

resulted in several IRB policy revisions. A

summary of those revisions follows on

page 2.

IMPORTANT MESSAGE:

VA personnel, including WOC and IPA appointees, must ensure oral notification of the ETSU/VA IRB immediately upon becoming aware of any local research death that is both unanticipated and related to the research. Written notification must be submitted to the IRB within 5 days of becoming aware of the death.

Review Policies 18, 25, 26 and 34 for detailed changes.

For flowcharts, etc., see:
<http://www.va.gov/ORO/oropubs.asp>

If you have questions, please contact Janine Olive at olivef@etsu.edu



EAST TENNESSEE STATE
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Summary of policy changes for investigators October 2015

The changes are all related to revisions of VA Handbook 1200.05 regarding reporting of events.

Policy 18:

1. Revises definition of serious adverse event, unanticipated, serious problem
2. Changes the events that are promptly reportable to the ETSU/VA IRB from "any local serious adverse event" to "any local serious adverse event that is both unanticipated and related to the research"
3. For VA studies, adds required prompt reporting to the ETSU/VA IRB of any serious problem that is both unanticipated and related to the research
4. Adds stricter reporting requirements of a local research death that is both unanticipated and related to the research:
 1. VA personnel, including WOC and IPA appointees, must ensure oral notification of the ETSU/VA IRB immediately upon becoming aware of any local research death that is both unanticipated and related to the research.
 2. VA personnel, including WOC and IPA appointees, must ensure written notification of the IRB within 5 business days of becoming aware of the death.

Policy 26

1. Revises definition of suspension, termination

Policy 25

1. Revises definition of serious non-compliance
2. VA personnel, including WOC and IPA appointees, must ensure that the IRB is notified, in writing, within 5 business days after becoming aware of any apparent serious or continuing noncompliance with IRB or other human research protection requirements.