East Tennessee State University
Office for the Protection of Human Research Subjects • Box 70565 • Johnson City, Tennessee 37614-1707
Phone: (423) 439-6053 Fax: (423) 439-6060

IRB APPROVAL – Initial Expedited Review

April 5, 2013

Kalie Nolen

Re: Meeting the Needs of Family Members of ICU Patients
IRB#: 0213.12s
ORSPA #:

The following items were reviewed and approved by an expedited process:

- New protocol submission form, ICD version date 2/1/2013, CV, Letter of support from Holston Valley, Survey,

The item(s) with an asterisk(*) above noted changes requested by the expedited reviewers.

On **April 5, 2013**, a final approval was granted for a period not to exceed 12 months and will expire on **April 4, 2014**. The expedited approval of the study *and* requested changes will be reported to the convened board on the next agenda.

The following **enclosed stamped, approved Informed Consent Documents** have been stamped with the approval and expiration date and these documents must be copied and provided to each participant prior to participant enrollment:

- Informed Consent Document (ICD version date 2/1/2013 stamped 4/5/2013)

Federal regulations require that the original copy of the participant's consent be maintained in the principal investigator's files and that a copy is given to the subject at the time of consent.

Projects involving Mountain States Health Alliance must also be approved by MSHA following IRB approval prior to initiating the study.

Unanticipated Problems Involving Risks to Subjects or Others must be reported to the IRB (and VA R&D if applicable) within 10 working days.

Proposed changes in approved research cannot be initiated without IRB review and approval. The only exception to this rule is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 10 working days) on Form 109 (www.etsu.edu/irb). The IRB will review the change to determine that it is consistent with ensuring the subject's continued welfare.

Sincerely,
George Youngberg, M.D., Chair
ETSU/VA Medical IRB