



Office of Research Compliance
Institutional Review Board
2000 Kraft Drive, Suite 2000 (0497)
Blacksburg, Virginia 24061
540/231-4991 Fax 540/231-0959
e-mail moored@vt.edu
www.irb.vt.edu

FWA00000572(expires 1/20/2010)
IRB # is IRB00000667

DATE: November 21, 2007

MEMORANDUM

TO: Eileen M. Van Aken
Jennifer Farris
Wiljeana Jackson Glover

Approval date: 12/16/2006
Continuing Review Due Date: 12/1/2007
Expiration Date: 12/15/2007

FROM: David M. Moore

SUBJECT: **IRB Amendment 3 Approval:** "An Empirical Investigation of Kaizen Event Effectiveness", OSP #477349, IRB # 05-439

This memo is regarding the above referenced protocol which was previously granted approval by the IRB on December 16, 2006. You subsequently requested permission to amend your IRB application. Since the requested amendment is nonsubstantive in nature, I, as Chair of the Virginia Tech Institutional Review Board, have granted approval for requested protocol amendment, effective as of November 21, 2007. The anniversary date will remain the same as the original approval date.

As an investigator of human subjects, your responsibilities include the following:

1. Report promptly proposed changes in previously approved human subject research activities to the IRB, including changes to your study forms, procedures and investigators, regardless of how minor. The proposed changes must not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
2. Report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
3. Report promptly to the IRB of the study's closing (i.e., data collecting and data analysis complete at Virginia Tech). If the study is to continue past the expiration date (listed above), investigators must submit a request for continuing review prior to the continuing review due date (listed above). It is the researcher's responsibility to obtain re-approval from the IRB before the study's expiration date.
4. If re-approval is not obtained (unless the study has been reported to the IRB as closed) prior to the expiration date, all activities involving human subjects and data analysis must cease immediately, except where necessary to eliminate apparent immediate hazards to the subjects.

As indicated on the IRB application, this study is receiving federal funds. The approved IRB application has been compared to the OSP proposal listed above and found to be consistent. Funds involving procedures relating to human subjects may be released. Visit our website at www.irb.vt.edu for further information

cc: File
T. Coalson 0118