Office of Research Compliance
Institutional Review Board
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FWA00000572(expires 1/20/2010)
IRB # is IRB00000667

DATE: December 3, 2008

MEMORANDUM

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

FROM: David M. Moore

Approval date: 12/16/2008
Continuing Review Due Date:12/1/2009
Expiration Date: 12/15/2009

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

This memo is regarding the above referenced protocol which was previously granted expedited approval by the IRB. The proposed research is eligible for expedited review according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. Pursuant to your request, as Chair of the Virginia Tech Institutional Review Board, I have granted approval for extension of the study for a period of exempt, effective as of December 16, 2008.

Approval of your research by the IRB provides the appropriate review as required by federal and state laws regarding human subject research. 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
OSP
T. Coalson 0118