DATE: February 18, 2010

MEMORANDUM

TO: George A. Clum
Kristine King

FROM: David M. Moore

SUBJECT: IRB Amendment 2 Approval: “A Treatment Feasibility Study of an Attention Retraining Approach for Trauma”, IRB # 09-477

This memo is regarding the above referenced protocol which was previously granted approval by the IRB on July 7, 2009. 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 February 18, 2010. 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.

cc: File