DATE:  January 21, 2009

MEMORANDUM

TO:  Thomas H. Ollendick
      Matthew Jarrett

FROM:  David M. Moore

SUBJECT:  IRB Expedited Continuation 1 of previous Full Review:  “The Treatment of Comorbid Attention-Deficit/Hyperactivity Disorder (ADHD) and Anxiety in Children”, IRB # 08-015

This memo is regarding the above referenced protocol which was previously granted Full IRB approval. The proposed continuing review request is eligible for expedited review according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. As Chair of the Virginia Tech Institutional Review Board, I have granted approval for extension of the study for a period of 12 months, effective as of February 11, 2009.

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.

cc:  File
      Department  Reviewer:  David W. Harrison