MEMORANDUM

TO: George W. Norton
   Jackline Bonabana

FROM: David M. Moore

DATE: April 12, 2007

SUBJECT: IRB Expedited Approval: “Health and Environmental Benefits of Reduced Pesticide Use in Uganda”, OSP #434320, IRB # 07-153

This memo is regarding the above-mentioned protocol. The proposed research 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 to the study for a period of 12 months, effective April 12, 2007.

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 obtained 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.

Important:
If you are conducting federally funded non-exempt research, this approval letter must state that the IRB has compared the OSP grant application and IRB application and found the documents to be consistent. Otherwise, this approval letter is invalid for OSP to release funds. Visit our website at http://www.irb.vt.edu/pages/newstudy.htm#OSP for further information.

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
   Department Reviewer: Kevin Boyle
   OSP