“HIV Testing Factors among Rural Among Rural Black Men (HiTFARM)”

Attachment 4c. Local IRB Approval – University of Kentucky

UK UNIVERSITY OF KENTUCKY

Office of Research Integrity
IRB, IACUC, RDRC
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Initial Review - Approval for UK investigator (Crosby) involvement only

Approval Ends
March 29, 2011

IRB Number
10-0205-F2L

TO: Richard A Crosby, Ph.D.
Unassigned
College of Public Health
121 Washington Ave., Rm 113C, 0003
(859)257-5678 ext. 82039

FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)

SUBJECT: Approval of Protocol Number 10-0205-F2L

DATE: June 18, 2010

On June 17, 2010, the Medical Institutional Review Board approved minor revisions requested at the convened meeting on March 30, 2010 for your protocol entitled:

HIV TESTING FACTORS AMONG RURAL/SMALL CITY BLACK MEN (HiTFARM)

Approval is effective from March 30, 2010 until March 29, 2011 and extends to any consent/assent form, cover letter, and/or phone script. If applicable, attached is the IRB approved consent/assent document(s) to be used when enrolling subjects. **[Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.]** Prior to the end of this period, you will be sent a Continuation Review Report Form which must be completed and returned to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigator's responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after IRB approval has been obtained, download and read the document "PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" from the Office of Research Integrity's Guidance/Policy Documents web page [http://www.research.uky.edu/ori/human/guidance.htm#PIresp]. Additional information regarding IRB review, federal regulations, and institutional policies may be found through ORI's web site [http://www.research.uky.edu/ori/]. If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at (859) 257-9428.

Chairperson/Vice Chairperson