

Friday, January 20, 2012

Dear Darrell Wheeler,

On Friday, January 20, 2012 the Loyola University Chicago Institutional Review Board (IRB) reviewed and approved your Initial application for the project titled "Critical Thinking and Cultural Affirmation (CTCA): Evaluation of a Locally Developed HIV Prevention Intervention ". Based on the information you provided, the IRB determined that:

- the risks to subjects are minimized through (i) the utilization of procedures consistent with sound research design and do not unnecessarily expose participants to risk, and (ii) whenever appropriate, the research utilizes procedures already being performed on the subjects for diagnostic or treatment purposes
- the risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result
- the selection of subjects is equitable
- informed consent be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116
- informed consent be appropriately documented, in accordance with, and to the extent required by §46.117
- when appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects
- when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
- when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects

Documented consent will be obtained from all subjects enrolled.

This review procedure, administered by the IRB, in no way absolves you, the researcher, from the obligation to adhere to all Federal, State, and local laws and the Loyola University Chicago policies. Immediately inform the IRB if you would like to change aspects of your approved project (please consult our website for specific instructions). You, the researcher, are respectfully reminded that the University's ability to support its researchers in litigation is dependent upon conformity with continuing approval for their work.

Please notify the IRB of completion of this research and/or departure from the Loyola University Chicago by submitting a Project Closure Report using the CAP system. In all correspondence with the IRB regarding this project, please refer to IRB project number #733 or IRB application number #718.

The IRB approval granted for this project expires on 1/18/2013 12:00:00 AM

If you have any questions regarding this approval, the IRB, or the Loyola University Chicago Human Subject Protection Program, please phone the Assistant Director for Research Compliance at (773) 508-2689 or email the IRB at irb@luc.edu.

Best wishes for your research,

Raymond H. Dye, Jr., Ph.D.

Chairperson, Institutional Review Board

Raymond N. Dy