To:

Kristie Holmes

From:

Randall W. Phillips, Ph.D. - Chair, Institutional Review Board

Protocol:

#0912-00589 "International ICT Applications for Women's Health"

This is to notify you that the Institutional Review Board has approved the above referenced protocol. This project was reviewed in accordance with all applicable statutes and regulations as well as ethical principles.

Approval of this project is given with the following obligations:

- When the project is finished or terminated, the attached Notice of Completion form must be completed and sent to Suzanne Barham, IRB Compliance Officer, UU Box 1815, Jackson, TN 38305 prior to the expiration date. This approval expires one year from the approval date, and must be renewed prior to that date if the study is ongoing.
- At the end of one year from the approval date, if the project is not finished or terminated, a
 Continuing Review application must be completed and approved to continue the project. If
 approval is not obtained, the human consent form is no longer valid and accrual of new
 subjects must stop.
- 3. Any adverse effects must be reported to the IRB on the Adverse Effects Form. Adverse events should be reported to the IRB within 10 working days. Examples include unexpected complications in a subject, missteps in the consent documentation, or breaches of confidentiality.
- 4. No change may be made in the approved protocol without board approval, except where necessary to eliminate apparent immediate hazards or threats to subjects. Such changes must be reported promptly to the board to obtain approval.
- 5. The stamped, approved human subjects consent form must be used (if applicable). Photocopies of the form may be made.

If you have any questions, please call the Institutional Review Board office at 731.661.5580. The forms referred to above can be found on the Institutional Review Board website at http://www.uu.edu/programs/irb/.

9/21/2012

Randall Phillips, Ph.D.

Chair, Institutional Review Board

Union University