COLUMBIA UNIVERSITY
SCHOOL OF NURSING

August 8, 2012

Ms. Diane Flournoy
Grants Management Officer
Centers for Disease Control and Prevention (CDC)
Procurement and Grants Office, Branch I
2920 Brandywine Rd. MS E15
Atlanta, GA 30341
Ph: (770) 488-2072 Fax: (770) 488-2868
E-mail: DFlournoy@cdc.gov

Re: Grant # 1 U01 PS003715-01, "Informing the Development of Mobile Apps for HIV Prevention, Treatment and Care," PI: R. Schnall

Dear Ms. Flournoy:

Attached please find Columbia University Medical Center Institutional Review Board approval for IRB Protocol # AAAK3559 for Grant # 1 U01 PS003715-01, "Informing the Development of Mobile Apps for HIV Prevention, Treatment and Care.

If you have any questions or require additional information, please feel free to contact me at 212-342-6886 or via e-mail at rb897@columbia.edu. We look forward to working with you on this project.

Sincerely,

Rebecca Schnall, RN, PhD
Assistant Professor of Nursing
Columbia University School of Nursing

Christopher Suarez
Project Officer
Sponsored Projects Administration
Columbia University

August 10, 2012

COLUMBIA UNIVERSITY MEDICAL CENTER

Institutional Review Board
(CU IRB)
722 W. 168th Street, 4th floor
New York, NY 10032
212.305.5883 Tel
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www.cumc.columbia.edu/dept/irb

Rebecca Schnall
NUR Nursing General - 800100X
617 West 168th Street

Protocol Number: IRB-AAAK3559
Title: Informing the Development of Mobile Apps for HIV Prevention, Treatment and Care
Approval Date: 08/05/2012
Expiration Date: 08/04/2013

Grant #: CDC PS12001

Dear Dr. Schnall,

On August 5, 2012, the above-mentioned study was reviewed and approved by the Chair or Designee of Columbia University Medical Center Institutional Review Board (IRB) Exp. It met the regulatory guidelines for expedited review, category 7. You may now begin human research for this study.

Reminder: According to the information provided in the RASCAL submission, the enrollment of non-English speaking participants is anticipated. Before non-English speaking participants can be enrolled, you will need to provide a translation of the IRB approved study documents in accordance with the CUMC IRB Enrollment of Non-English Speaking Subjects policy, http://www.cumc.columbia.edu/dept/irb/policies/Nonenglish_Speaking_Subjects.rtf.

The requirement to obtain parental permission has been waived by the IRB in accordance with 45 C.F.R. § 46.116(d).

During the approval period, all subjects enrolled not only must provide voluntary informed consent to participate in the study, but also must sign a copy of the appropriate stamped consent document(s). A copy of the consent document(s) must be given to the subjects for their record.

The following study-related materials were approved:
- Consent Forms (CF-AAAL2712, CF-AAAL2735, CF-AAAL2737) and Assent Forms (CF-AAAL2711 and CF-AAAL2736)
- HIPAA Form HIP-AAAH2308
- Telephone and Email Invitation for heuristic evaluators, attached 07/25/2012
- Recruitment Flyer - PLWH - Usability Testing, attached 07/09/2012
- Recruitment Flyer - PLWH - Focus Groups, Design Sessions, attached 07/09/2012
- Recruitment Flyer - MSM- Usability Testing, attached 07/09/2012
- Recruitment Flyer - MSM- Focus Groups and Design Sessions, attached 07/09/2012
- Recruitment Flyer - HIV Providers- Focus Groups and Design S, attached 07/09/2012
- Interview Guide - Design Session - PLWH, attached 07/09/2012
- Interview Guide - Design Session - MSM, attached 07/09/2012
- Focus Group Guide PLWH, attached 07/09/2012
- Focus Group Guide - MSM, attached 07/09/2012
- Focus Group Guide Providers, attached 07/09/2012
- Post Study System Usability, attached 07/06/2012
- HIV Stigma, attached 07/06/2012
- Heuristic Evaluation Form, attached 07/06/2012
- Perceived Ease of Use and Usefulness, attached 07/06/2012
- Information Privacy Concerns, attached 07/06/2012
- HIV medical history, attached 07/06/2012
- Demographic, attached 07/06/2012
- SF-12, attached 07/06/2012

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Any proposed changes in the protocol must be immediately submitted to the IRB for review and approval prior to implementation, unless such a change is necessary to avoid immediate harm to the participants. Additionally, any unanticipated problems that involve risks to subjects must be reported to the IRB in accordance with the CUMC Unanticipated Problems: Reporting to the IRB of Unanticipated Problems Involving Risks policy, dated January 24, 2008. All submissions for modifications and unanticipated problems must be submitted through RASCAL.

Renewal applications should be submitted 60 days before the expiration date of this study through RASCAL. Failure to obtain renewal of your study prior to the expiration date will require discontinuance of all research activities for this study, including enrollment of new subjects. You must inform the IRB in writing when your study has been completed.

If you have any questions regarding this approval, please contact Susie Kim at (212) 342-3058 or sjk2142@columbia.edu.

Columbia University appreciates your commitment towards the ethical conduct of human research.

Sincerely,

Susie J. Kim, CIP
Manager, IRB 5-Expedited

Electronically signed by: Kim, Susie