Attachment 4a. Local IRB Approval – Colorado IRB

Colorado Multiple Instititutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
13001 E. 17th Place, Building 500, Room N3214
Aurora, Colorado 80045

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University of Colorado Hospital
Denver Health Medical Center
Veteran's Administration Medical Center
The Children's Hospital
University of Colorado Denver
Colorado Prevention Center

Certificate of Approval

07-Jul-2011

Investigator:	Alia Al-Tayyib
Sponsor(s):	Centers for Disease Control and Prevention/DHHS~
Subject:	COMIRB Protocol 11-0425 Initial Application
Effective Date:	28-Jun-2011
Expiration Date:	27-Jun-2012
Expedited Category:	6,7
Title:	Demonstration Project Of Hcv Rapid Tests In Hiv Testing Settings

All COMIRB Approved Investigators must comply with the following:

- For the duration of your protocol, any change in the experimental design/consent and/or assent form must be approved by the COMIRB before implementation of the changes.
- Use only a copy of the COMIRB signed and dated Consent and/or Assent Form. The investigator bears the responsibility for obtaining from all subjects "Informed Consent" as approved by the COMIRB. The COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form. Consent and/or assent forms must include the name and telephone number of the investigator.
- Provide non-English speaking subjects with a certified translation of the approved Consent and/or Assent Form in the subject's first language.
- The investigator also bears the responsibility for informing the COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policy and Procedures.
- Obtain COMIRB approval for all advertisements, questionnaires and surveys before use.
- Federal regulations require a Continuing Review to renew approval of this project within a 12-month period from the last approval date unless otherwise indicated in the review cycle listed below. If you have a restricted/high risk protocol, specific details will be outlined in this letter. Non-compliance with Continuing Review will result in the termination of this study.

You will be sent a Continuing Review reminder 75 days prior to the expiration date. Any questions regarding this COMIRB action can be referred to the Coordinator at 303-724-1055 or UCHSC Box F-490.

Review Comments:

This Expedited Approval Includes -
Application
Attachments - A, F
1 Staff Consent Form
1 Client Consent Form
Protocol

Focus Group and Interview Guide
Client and Staff Recruitment Scripts

IRB Authorization Agreement us as Institution A and ALERT Health Inc.

Grant CDC

Affiliated Site - Denver Health Medical Center
Non-Affiliated Site - Alert Health

Sincerely,

UCD Panel B