UNM HEALTH SCIENCES CENTER

Human Research Review Committee
Human Research Protections Office

April 13, 2015

Kimberly Page, PhD, MPH
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Albuquerque, NM 87106
505-272-2520
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Dear Dr. Page:

On 3/3/2015, the HRRC reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	Hepatitis Treatment and Integrated Prevention
Investigator:	Kimberly Page, PhD, MPH
Study ID:	14-313
Submission ID:	14-313
Funding:	CDC
Funding Source ID:	5U18PS004568-02
Grant ID:	3T910
IND, IDE, or HDE:	None
Submission Summary:	Initial Study
Documents Approved:	Protocol v03/12/2015 Combined Consent/HIPAA Form v03/12/2015 H-TIPS Appendix 1-Survey v04/07/2015 H-TIPS Appendix 2-HCF Reinfection Interview Guide v12/08/2014 H-TIPS Appendix 3-Study Timelines v12/08/2014 H-TIPS Appendix 4-Study Visit Reminders v12/08/2014 Flyer v04/10/2015 Patient Authorization for Discloure of PHI submitted 01/29/2015
Review Category:	Full Committee
Determinations/Waivers:	Requires a signed Consent form. HIPAA Authorization on record; signed HIPAA required. Consent and HIPAA included in same document.
Submission Approval Date:	3/3/2015
Approval End Date:	3/2/2016
Effective Date:	4/13/2015

The HRRC approved the study from 3/3/2015 to 3/2/2016 inclusive. If modifications were required to secure approval, the effective date will be later than the approval date. The "Effective Date"

4/13/2015 is the date the HRRC approved your modifications and, in all cases, represents the date study activities may begin.

Before 3/2/2016 or within 45 days of study closure, whichever is earlier, you are required to submit a continuing review. You may submit a continuing review by navigating to the active study and clicking the "Create Modification / CR" button.

Please use the consent documents that were approved and stamped by the HRRC. The stamped and approved consents are in a comment within the submission covered by this approval letter.

This determination applies only to the activities described in this submission and does not apply should you make any changes to these documents. If changes are being considered and there are questions about whether HRRC review is needed, please submit a study modification to the HRRC for a determination. A change in the research may disqualify this research from the current review category. You can create a modification by clicking Create Modification / CR within the study.

In conducting this study, you are required to follow the Investigator Manual dated July 31, 2012 (HRP-103), which can be found by navigating to the IRB Library.

Sincerely,

Mark Holdsworth, PharmD
Executive Chair