



Banner Health®

FWA #00002630

IORG #0004299

October 20, 2014

Anil B Seetharam, MD
Attn: Aeriol Ryane
Banner Liver Disease Center (Edwards)
1300 N. 12th Street: Ste. 404
Phoenix, AZ 85006

RE: Project # 01-14-0113 An Analysis of Direct Acting Antiviral Therapy against Hepatitis C and Influence on Components of the Metabolic Syndrome
iRIS Reference # 015327
IRB Expedited Approval – New Protocol (Version 1.1 dated 10/15/14), Waiver of Informed Consent and HIPAA Authorization

Dear Dr. Seetharam:

This letter serves to notify you the above referenced **Protocol, request for waiver of Informed Consent, and waiver of HIPAA Authorization** received expedited review and approval by Marc Lee, MD, Chair of the Banner Health Institutional Review Board (Phoenix Panel) on October 20, 2014 for conduction at Banner Good Samaritan Medical Center and Banner Transplant and Advanced Liver Disease Center. This expedited review was performed in accordance with 21CFR56.110 (b) and/or 45CFR46.110(b). This study has received approval for one year. Federal regulations require all studies be reviewed at least annually. It was determined all the specified criteria for a waiver of Research Authorization were met. It is recognized the request meets the following requirements for waiver of authorization:

- Use and disclosure involves no more than minimal risk to the patients
- The research could not practicably be conducted without the waiver
- The research could not be conducted without the use of the PHI
- The privacy risks are reasonable in relation to the anticipated benefits

The Board's approval to conduct your study will expire on **October 20, 2015**. The IRB requests that you submit a Continuing Review report one month prior to the October 20, 2015 IRB meeting. This allows time for processing and review prior to the IRB expiration date of the study.

Any internal unanticipated problems or unexpected drug/biologic adverse events must be reported to the IRB within 7 working days of the investigator learning of the event.

If you wish to change any aspect of this study, such as the procedures or the investigators, please communicate your requested changes to the Board. The new procedure is not to be initiated until the IRB approval has been given.

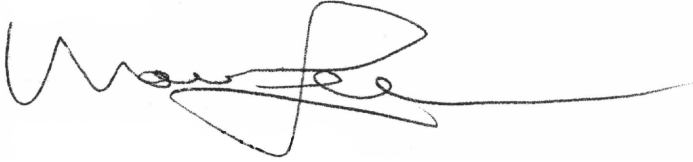
Unusual events, results of the study or any additional information relative to the study must be submitted to the Board. A Closing report is required upon completion of the project. In the event the study results are published, please send a copy to the Banner Research so it may be included in the file. A copy of this letter will be retained electronically.

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The Board appreciates your participation in research. If you have any questions, please contact Jane Hoverson, CIM, CRC, Research Regulatory Specialist, at (480) 412-4083.

Sincerely,

A handwritten signature in black ink, appearing to read 'Marc Lee', with a long horizontal line extending to the right.

Signature applied by Marc Lee on 10/20/2014 06:47:39 PM MST

Marc Lee, MD
Chair, Banner Health IRB (Phoenix Panel)

ML/jh
cc: Research Director

This study was reviewed and approved by the Banner University Medical Center – Phoenix Institutional Review Board.