September 21, 2016

To: Lynne Hopkins, MD
Protocol Title: Harvoni for HIV/HCV co-infection with advanced fibrosis or cirrhosis
Protocol #: 160037HD

Submission Type: Initial Review
Review Type: Convened Procedures

Approval Date: September 21, 2016
Expiration Date: September 20, 2017

The Department of Health Institutional Review Board has reviewed and approved your /application, including the f/following documents:

- Protocol v.1 dated 8/17/16
- Data collection form v.1 dated 8/15/16
- Health risk survey/questionnaire dated 7/1/16
- Signed local site support dated 8/12/16
- Florida state resident practice approval letter dated 4/23/15
- Informed consent dated 8/17/16

Please keep in mind:

- Apply for continuing review at least 60 days prior to expiration, even if your study is closing.
- Report all problems listed below as soon as possible, but no later than five working days.
- If you need to make changes to your study, complete the modification application.
- If you have to make a change to eliminate hazard to human subjects and there is not time to submit a modification, notify the IRB as soon as possible but no later than five working days.

If you have questions, want to offer suggestions, or talk with someone about this or other projects, please contact Rotanya Bryan or Bonnie Gaughan-Bailey at the Department of Health IRB at (850) 245-4585 or toll-free in Florida (866) 433-2775.

Thank you for your cooperation with the IRB.

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

Sincerely,

Bonnie Gaughan-Bailey, MPA
Administrator
Biomedical Research Section
Public Health Research

Reportable Events

Report the following problems to IRB Staff, as soon as possible, but within five business days:

- Adverse events and adverse outcomes which in the opinion of the principal investigator are both unexpected and related and suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized.
- Any interim analysis or safety monitoring report indicating the frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
- Any breach of confidentiality.
- Any change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
- Any change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
- Any incarceration of a participant in a protocol not approved to enroll prisoners.
- Any event that requires prompt reporting to the sponsor.
- Any sponsor imposed suspension for risk.
- Any protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm or has the potential to recur.
- Any unanticipated adverse device effect.
- Any non-compliance identified by Department of Health audit or monitoring.
- Any investigation by FDA or OHRP or other federal agency of research (not just including this study) by any researcher on the study.
- Any loss of license or hospital privileges by any researcher on the study.

Contact IRB staff to obtain answers to questions, express concerns, and convey suggestions regarding the HRPP by emailing irb@flhealth.gov or calling 850-245-4585.