Institutional Review Board - Federalwide Assurance #00003152

University of Cincinnati

Date: 5/18/2015

From: UC IRB

To: Principal Investigator: Judith Feinberg
COM IM INF IDC

Re: Study ID: 2014-7919
Study Title: Southern Ohio Prevents Hepatitis (StOPHeP)

The above referenced protocol was reviewed and given **CONDITIONAL APPROVAL** by the convened IRB on 5/6/2015.

Response to the conditions and revisions to all applicable additional documentation provided to the IRB were reviewed using an **EXPEDITED** review procedure as set forth in 45 CFR 46.110 (b) on 5/15/2015.

Study Documents

CDC_StOPHeP_Brochure_4 8 15.pptx
CITI Training Joe Gay
CITI Training Lisa Roberts
COIs
Consent dated 051215 w IRB requests
IRB Authorization Agreement-Cinti Exchange Program
IRB Authorization Agreement-Health Recovery Services
IRB Authorization Agreement-Portsmouth City Health Dept.
Joe Gay CITI 1-27-15.pdf
Letter to IRB Chairman
Protocol Version Date 051215
ReleaseInformation(ROI)_apr7.docx
Response to IRB issues 051215.doc
StOPHeP_Locator Information Form_revisions4 7 15.docx
stophep_responseirb_apr10 (2).docx
stophepinstrument_UCIRB_apr2015.docx

The conditions of approval have now been satisfied and **FULL APPROVAL** is granted.

This study will be due for continuing review at least 30 days before 5/5/2016.

Please note the following requirements:

Per 45 CFR 46.116 (21 CFR 50.20) the IRB has determined that informed consent must be obtained from all adult participants and that this consent must be documented by signature on the IRB approval consent form.

There are no items to display

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There are no items to display

It is understood that the information defined by HIPAA as Protected Health Information (PHI) that will be collected as part of this study will only be used and/or disclosed consistent with the information provided in the Authorization to Use and Disclose PHI section of the informed consent.

AMENDMENTS: The principal investigator is responsible for notifying the IRB of any changes in the protocol, participating investigators, procedures, recruitment, consent forms, FDA status, or conflicts of interest. Approval is based on the information as submitted. New procedures cannot be initiated until IRB approval has been given. If you wish to change any aspect of this study, please submit an Amendment via ePAS to the IRB, providing a justification for each requested change.

CONTINUING REVIEW: The investigator is responsible for submitting a Continuing Review via ePAS to the IRB at least 30 days prior to the expiration date listed above. Please note that study procedures may only continue into the next cycle if the IRB has reviewed and granted re-approval prior to the expiration date.

UNANTICIPATED PROBLEMS: The investigator is responsible for reporting **unanticipated problems** promptly to the IRB via ePAS according to current reporting policies.

STUDY COMPLETION: The investigator is responsible for notifying the IRB by submitting a Request to Close via ePAS when the research, including data analysis, has completed.

Please note: This approval is through the IRB only. You may be responsible for reporting to other regulatory officials (e.g. VA Research and Development Office, UC Health – University Hospital). Please check with your institution and department to ensure you have met all reporting requirements.

Statement regarding International conference on Harmonization and Good clinical Practices. The Institutional Review Board is duly constituted (fulfilling FDA requirements for diversity), has written procedures for initial and continuing review of clinical trials: prepares written minutes of convened meetings and retains records pertaining to the review and approval process; all in compliance with requirements defined in 21 CFR Parts 50, 56 and 312 Code of Federal Regulations. This institution is in compliance with the ICH GCP as adopted by FDA/DHHS.

Thank you for your cooperation during the review process.