TO: Chari Cohen (Hepb.org)
CC: Yasmin Ibrahim
FROM: S. J. Maberry, Director
DATE: August 11, 2022
SUBJECT: Attitudes and Perceptions of People Living with Hepatitis B on Participation in Clinical Trials
RE: Approval for HIRB project No. 081122-407

The **Heartland Institutional Review Board** (HIRB) is in receipt of all required documentation from Hepb.org and has completed the review process of the project: Attitudes and Perceptions of People Living with Hepatitis B on Participation in Clinical Trials, now referred to as **HIRB Project No**. **081122-407.**

The goal of this project is to systematically, using evidence-based public health research strategies, document the knowledge, perceptions, challenges, and barriers to clinical trial participation among people living with CHB, so that partners in the drug development, federal partners (FDA, NIH, CDC, OMH), nonprofit researchers, and community coalitions can use this information to help inform drug and clinical trial development. This mixed-methods study focuses on people living with CHB, employing key informant interviews, an online survey, focus groups, and individual interviews to collect and analyze robust data. Specific objectives include:

1. To understand how people living with CHB perceive clinical trials and to assess barriers and challenges to clinical trial participation, specifically among Asians, Pacific Islanders, and those of African origin.
2. To better understand patient perspectives about risk/benefit tradeoffs related to CHB clinical trials and patient thoughts on priority treatment outcomes (including patient-focused outcomes related to improved quality of life).
3. To document strategies that can improve clinical trial participation among diverse people living with CHB, including strategies to improve clinical trial design to make them more patient-centric and strategies to improve communication towards promoting participation.

The documentation provided meets the DHHS policy guidelines of 45 CFR §46.111. As submitted, this study has been approved and classified as follows:

[X] There is no more than minimal risk to the subjects.
[ ] There is greater than minimal risk to the subjects.

This approval applies only to the proposal currently on file for one year from the date of approval, as indicated by the date of this letter. (**August 11, 2023**) If this study is to be extended past said date, please complete an online extension form from our website and submit it no less than 30 days before the one-year deadline. Any changes in the study or protocol(s) that affect human subjects (the participants) must be reviewed and approved by HIRB before implementation. Injuries or any unanticipated events involving risk to human subjects (participants) or others involved with the project must be reported within ten calendar days to the HIRB Director in writing using the appropriate form available on the HIRB website.

Note that all researchers/investigators involved in this research study must maintain on file with Heartland IRB either the Heartland IRB Human Subjects Assessment Certificate offered through the HIRB website or an HIRB-approved training completion certificate before engaging in this study. Use only the Heartland IRB-approved protocols, consent forms, and instruments for this research study. Include the HIRB approval statement text on all project materials as provided below.

This project has been reviewed and approved by the Heartland Institutional Review Board.

Questions concerning your rights as a participant in this research may be addressed to the Executive Director at Heartland IRB. Office: (866) 618-HIRB [4472]; Fax: (866) 414-0517; or by emailing director@heartlandirb.org.

Also, before involving any human subjects (participants), properly executed consent forms must be obtained from each subject and/or authorized representative. Such documentation of informed consent must be kept on file and made available at any time to authorized HIRB representatives performing an on-site audit. Each participant must also be provided a copy of all consent forms and project information materials for their records.

In addition, before involving any human subjects at additional sites other than those provided initially, Heartland Institutional Review Board must receive electronic copies of permission letters from each site's supervisor. These letters may be in a standardized format. Still, they must include a short description of the research project, the name of the organization at whose site the study will take place, the address of said site and location within the site where activities will occur, and name, title, contact information, and signature of designated site supervisor authorized to grant permission.

The research activities described below have been approved for those consenting/assenting to be in this study:

1. Protocol Review HBF 2022 Improving Diversity of Participants in CTs 08.09.22
2. Clinical Trail Participation Moderator Guide 07.25.2022
3. English Clinical Trial Participation Survey Final 06.06.2022
4. Online Survey Invite 05.06.2022
5. Consent Form Diversity of Clinical Trial Participation 08.09.2022

Also included were the following items:

- Investigator Review form (Cohen),
- HIRB IRB Certificate or other Human Subjects training (*on file*),
- CV/Resume (Cohen, Ibrahim),

Best wishes for the success of your research project.

Cordially,

S. J. Maberry
Director, Heartland IRB
director@heartlandirb.org

My signature above verifies that the IRB listed below operates in accordance with all applicable laws, regulations, and guidelines for human subject research. We maintain compliance with Title 21, Code of Federal Regulations (21 CFR) Parts 50 (Protection of Human Subjects) and 56 (Institutional Review Boards), DHHS 45 CFR Parts 46.101-124, International Conference of Harmonization (ICH), and Good Clinical Practices (GCP) guidelines.

We are registered with the Department of Health and Human Services. Our Parent Institution/Organization is IORG0006400. Our IRB registration is number IRB00007694. Our Federal Wide Assurance number is FWA00023407. The expiration date of our IRB registration is 06/02/2023.

Heartland Institutional Review Board, LLC
4226 Woodfield Place, Suite 100
Swansea IL 62226-7800