

The HBRN Adult Study Data Archive

The HBRN Adult Archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Check.

Archive files are organized into the following directories:

- Documents
- Forms
- Data
- Dataset Integrity Check (DSIC)

Documents

The HBRN Adult Documents directory contains:

- Adult Cohort Study Protocol_v6.0_20130114.pdf – Protocol for the HBRN Adult Study
- HBRN Adult Cohort Baseline Paper Additional Information.pdf – Gives additional details about certain variables in the data
- HBRN Adult Cohort Data Collection Timeline v1.4.pdf – Timeline of forms and sample collection used during the study
- HBRN Publications 20150424.docx – List of HBRN published manuscripts as of April 24, 2015
- MOP – This folder contains manuals of operations (instructions) for the following forms:
 - Baseline Evaluation - Coordinator (BC)
 - Baseline Evaluation – Investigator (BI)
 - Baseline Evaluation – Patient (BP)
 - Enrollment Criteria (EC)
 - Follow-Up Events (FE)
 - Follow-Up 12-Week Evaluation (FW)
 - Screening Log (SL)

Forms

The HBRN Adult Forms directory contains:

- BC_Baseline_Evaluation_v1_codbook.pdf – Annotation version of the Baseline Evaluation-Coordinator form
- BI_Baseline_Evaluation_v1_codbook.pdf – Annotation version of the Baseline Evaluation-Investigator form
- BP_Baseline_Evaluation_v1_codbook.pdf – Annotation version of the Baseline Evaluation-Patient form
- EC_Enrollment_Criteria_v1_codbook.pdf – Annotation version of the Enrollment

Criteria form

- FE_Followup_events_v1.1_codbook.pdf – Annotation version of the Follow-Up Events form
- FW_Followup_evaluation_12week_v1.0_codbook.pdf – Annotation version of the Follow-Up 12-Week Evaluation form
- SL_Screening_Log_V4.0.pdf – Screening Log form

Data

The HBRN Adult data directory contains the following files, and the following raw datasets in Windows-based SAS, v.7-8-9 format:

- HBRN Formats.sas – List of formats used in the HBRN data
- hbrn_bc.sas7bdat – This dataset contains 1782 observations with variables from the Baseline Evaluation – Coordinator form. Data includes information about baseline labs (albumin, ALT, AST, creatinine, hemoglobin, etc.), family medical history, history of HBV treatment, medications being taken, and HBV DNA level.
- hbrn_bi.sas7bdat – This dataset contains 1776 observations from the Baseline Evaluation – Investigator form. Data includes duration of HBV infection, presumed source of Hepatitis B, Hepatitis B phenotype, and number of STDs.
- hbrn_bp.sas7bdat – This dataset contains 1779 observations from the Baseline Evaluation – Patient form. Data includes race, tobacco and drug use, alcohol use, and gender.
- hbrn_cdc_results.sas7bdat – This dataset contains 1682 observations, and contains information about the Hepatitis B virus genotype and subgenotype, and site transfers during the study.
- hbrn_ec.sas7bdat – This dataset contains 1784 observations from the Enrollment Criteria form. Data includes information about whether or not a subject was eligible for enrollment in the HBRN study, based off of certain criteria: history of hepatocellular carcinoma, history of hepatic decompensation, known HIV co-infection, use of current HBV antiviral therapy or chronic immunosuppression therapy, and if the PI has determined that the subject is suitable for the study.
- hbrn_fe.sas7bdat – This dataset contains 423 observations from the Follow-Up Events form. Data includes information about ALT flares, cirrhosis evidence, death, HBeAg, HBsAg, hepatocellular carcinoma, hepatic decompensation, liver transplants, and reasons for withdrawal from the HBRN study.
- hbrn_fw.sas7bdat – This dataset contains 1284 observations from the Follow-Up 12-Week Evaluation form. Data includes information regarding ALT, HBV DNA level, and samples and consents obtained.
- hbrn_screen_info.sas7bdat – This dataset contains 7636 observations and includes information about screening. This includes whether or not a subject is eligible to participate in the HBRN study based off of: history of HCC, history of hepatic decompensation, known HIV infection, history of liver transplants, age, and consent obtained.

- hbrn_sl.sas7bdat – This dataset contains 7636 observations from the Screening Log form. Data includes race, ALT levels, HBV DNA level, gender, consents given, and all eligibility criteria.
- hbrn_uwash_results.sas7bdat – This dataset contains 9413 observations, with results from various tests (including HBV DNA, HBeAg, and HBsAg) performed by the central lab during the HBRN study.

Data \Contents

This subdirectory contains contents of the datasets in the Data directory.

DSIC

The HBRN Adult Data Integrity Check (DSIC) directory contains:

- HBRN_Adult_DSIC.pdf- A report of an examination of the HBRN Adult Cohort datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Table 1 from the paper ‘The Hepatitis B Research Network (HBRN): Characteristics of the Adult Cohort in North American Reflect the Diversity in Country of Origin and Genotype’ by Ghany et al. Published results from the HBRN data were compared to values recalculated from HBRN archived analysis datasets in the NIDDK repository.