

The HBRN Pediatric Study Data Archive

The Hepatitis B Research Network (HBRN) Pediatric Archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Check.

Archive files are organized into the following directories:

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

Documentation

The HBRN Pediatric Documentation directory contains:

- Pediatric Cohort Study Protocol_v3.2.pdf – Protocol for the HBRN Pediatric Study
- HBRN Peds Cohort Baseline Paper Additional Information.pdf – Gives additional details about certain variables in the data
- HBRN Pediatric Cohort Data Collection Timeline v1.2.pdf – Timeline of forms and sample collection used during the study
- Bibliography.docx – List of HBRN published manuscripts as of 9/22/2015
- HBRN Public Website URL.pdf – Link to the Hepatitis B Research Network study website
- Manuals of Operation – This folder contains manuals of operations (instructions) for the following forms:
 - Baseline Evaluation (Pediatric) – Coordinator (BCP)
 - Baseline Evaluation (Pediatric) – Investigator (BIP)
 - Baseline Evaluation (Pediatric) – Patient (BPP)
 - Enrollment Criteria (Pediatric) (ECP)
 - Follow-Up Events (Pediatric) (FEP)
 - Screening Log (Pediatric) (SLP)

Forms

The HBRN Pediatric Forms directory contains:

- BCP_Baseline_Evaluation_v1.4_codbook.pdf – Annotated version of the Baseline Evaluation (Pediatric) - Coordinator form
- BIP_Baseline_Evaluation_v1_codbook.pdf – Annotated version of the Baseline Evaluation (Pediatric) - Investigator form
- BPP_Baseline_Evaluation_v1_codbook.pdf – Annotated version of the Baseline Evaluation (Pediatric) - Patient form
- ECP_Enrollment_Criteria_v1.1_codbook.pdf – Annotated version of the Enrollment

Criteria (Pediatric) form

- FEP_Followup_events_v1.1_codbook.pdf – Annotated version of the Follow-Up Events (Pediatric) form
- SLP_Screening Log_V1.2_codebook.pdf – Annotated version of the Screening Log (Pediatric) form

Data

The HBRN Pediatric 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 Pediatric data
- hbrn_bcp.sas7bdat – This dataset contains 348 observations with variables from the Baseline Evaluation (Pediatric) – Coordinator form. Data includes baseline labs, history of HBV treatment, medications being taken, and HBV DNA level.
- hbrn_bip.sas7bdat – This dataset contains 340 observations from the Baseline Evaluation (Pediatric) – Investigator form. Data includes duration of HBV infection, presumed source of Hepatitis B, and Hepatitis B phenotype.
- hbrn_bpp.sas7bdat – This dataset contains 345 observations from the Baseline Evaluation (Pediatric) – Patient form. Data includes race, gender, and socio-demographic information.
- 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_ecp.sas7bdat – This dataset contains 348 observations from the Enrollment Criteria (Pediatric) 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_fep.sas7bdat – This dataset contains 59 observations from the Follow-Up Events (Pediatric) 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_peds_ages.sas7bdat – This dataset contains 343 observations and includes the ages for each subject included in the analysis for the baseline manuscript.
- hbrn_slp.sas7bdat – This dataset contains 462 observations from the Screening Log (Pediatric) form. Data includes race, ALT levels, gender, consents given, and all eligibility criteria.
- hbrn_uwash_results.sas7bdat – This dataset contains 13,381 observations, with results from various tests (including HBV DNA, HBeAg, and HBsAg) performed by the central lab during the HBRN Pediatric study.
- Contents.pdf – Content listing of all datasets in the Data directory.

DSIC

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

- HBRN_Pediatric_Baseline_DSIC.pdf- A report of an examination of the HBRN Pediatric Cohort datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Table 1, Table 2, and the Supplemental Table from the paper ‘Children with Chronic Hepatitis B in the US and Canada in the Hepatitis B Research Network’ by Schwarz et al. Published results from the HBRN Pediatric data were compared to values recalculated from HBRN Pediatric archived analysis datasets in the NIDDK repository.