

The NASH NAFLD Pediatric Study Data Archive

The Nonalcoholic Steatohepatitis (NASH) Nonalcoholic Fatty Liver Disease (NAFLD) Pediatric Archive contains the Protocol, Standard Operating Procedures, Forms, Study data, and Dataset Integrity Check.

Archive files are organized into the following directories:

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

Documents

The NASH NAFLD Pediatric Documents directory contains:

- NAFLD_Database_Protocol.pdf – Protocol for the NAFLD Database
- NASHCRN_Bibliography.pdf – Published Manuscripts by the NASH CRN as of February 25, 2016
- Peds_Database_Consent.pdf – Consent statement for pediatrics for the NAFLD Database
- Peds_Database_Genetic_Consent.pdf – Genetic consent statement for pediatrics for the NAFLD Database
- Peds_Database_SOPs.pdf – Standard Operating Procedures for the NAFLD Database

Forms

The NASH NAFLD Pediatric Forms directory contains:

- Pediatric_Database_Forms.pdf – This document contains the following forms that were used for the NAFLD Pediatric Database collection. Note that multiple copies of the same form represent different versions of that form.
 - AD1 – Alcohol Use Disorders Identification Test (AUDIT)
 - DR1 – Death Report Form
 - HI1 – Followup Medical History Form
 - IE1 – Interim Event Report
 - IR1 – Liver Imaging Studies Report
 - LP1 – Symptoms of Liver Disease (Children)
 - MA1 – Modifiable Activity Questionnaire
 - MV1 – Missed or Incomplete Visit Form
 - PF2 – Focused Physical Examination Form
 - BC1 – Blood Collection for DNA Form
 - BG1/BG2/BG3 – Baseline History Form
 - BP1 – Blood Processing for Plasma and Serum Form

- CG1 – Genetic Consent Documentation
- CR1 – Central Histology Review Form
- ED1/ED2 – Database Enrollment Form
- LR1/LR2/LR3 – Laboratory Results – Tests Done During Screening and Followup Form
- LS1 – Laboratory Results – Tests Done only During Screening Form
- LT1 – Liver Tissue Banking Form
- PE1/PE2 – Physical Examination Form
- RG1 – Registration Form

Data

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

- Analysis_Data – This folder contains the following analysis datasets, used to create tables 1, 2, 3, 4, and 5 from the paper “Clinical Correlates of Histopathology in Pediatric Nonalcoholic Steatohepatitis”, published in Gastroenterology in 2008 by Patton et al.:
 - peds.sas7bdat
- Raw_Data – This folder contains the following raw datasets, corresponding to the form with the same name. Note that the forms for the pq.sas7bdat, pr.sas7bdat, ps.sas7bdat, pt.sas7bdat, pv.sas7bdat, pw.sas7bdat, and py.sas7bdat datasets are not included due to copyright (pv.sas7bdat, pw.sas7bdat, and py.sas7bdat correspond to pediatric Quality of Life forms for various ages; pq.sas7bdat, pr.sas7bdat, ps.sas7bdat, and pt.sas7bdat correspond to parent pediatric Quality of Life forms for various ages).
 - ad.sas7bdat
 - bg.sas7bdat
 - cr.sas7bdat
 - dr.sas7bdat
 - hi.sas7bdat
 - ie.sas7bdat
 - ir.sas7bdat
 - lp.sas7bdat
 - lr.sas7bdat
 - ls.sas7bdat
 - ma.sas7bdat
 - mv.sas7bdat
 - pe.sas7bdat

- pf.sas7bdat
- pq.sas7bdat
- pr.sas7bdat
- ps.sas7bdat
- pt.sas7bdat
- pv.sas7bdat
- pw.sas7bdat
- py.sas7bdat
- rg.sas7bdat
- Contents – This folder contains the following documentation:
 - NASH_NAFLD_Pediatric_Data_Dictionary.pdf – Contents for all of the datasets (both raw and analysis) listed above

DSIC

The NASH NAFLD Pediatric Data Integrity Check (DSIC) directory contains:

- NAFLD_Pediatric_Analysis_DSIC.pdf - A report of an examination of the ‘peds’ dataset (Patton paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the NASH NAFLD Pediatric data were compared to values recalculated from NASH NAFLD Pediatric archived analysis datasets in the NIDDK repository.
- NAFLD_Pediatric_Full_DSIC.pdf – A report of an examination of the raw datasets for completeness by statisticians and quality control specialists at the Repository. Published results from the NASH NAFLD Pediatric data were compared to values recalculated from the NASH NAFLD Pediatric archived raw form datasets in the NIDDK repository.

SAS Programs

This subdirectory contains the SAS program which created the analysis data set located in the Data\Analysis_Data directory.