

The FHN Daily Study Data Archive

The FHN Daily 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 FHN Daily Documents directory contains:

- DailyProtocol_7.2.08_v2.3.1.pdf – FHN Daily Protocol
- FHN_Bibliography.pdf – FHN Published Manuscripts
- FHN_Daily_MOP.pdf – FHN Daily Manual of Operations
- Explanation of Variable Windows.pdf – Contains information regarding schedule of follow-up visits, and which dates are used to record certain variables

Forms

The NASH PIVENS Forms directory contains:

- Forms_FHN_Daily.pdf – Includes a schedule for when certain forms are completed during the study, and multiple forms for the FHN Daily study, including:
 - F104: Co-Morbidity and Medical History Form
 - F105: Baseline Demographics, Employment, and Income Form
 - F107: Direct Patient Content Form
 - F108: U.S. Patient Future Linkage Form
 - F110: Daily Trial Eligibility Confirmation (Screening) Form
 - F111: Documentation of Six Consecutive Days Form
 - F112: Daily Trial Pre-Randomization Drop-out Form
 - F113: Daily Study Ready for Randomization Confirmation
 - F202: Amputation Form
 - F203: Monthly IV Iron Therapy
 - F204: Injectable Medications Form
 - F205: Medications and Supplements Form
 - F206: Residual Renal Function
 - F207: Biochemistry Laboratory Data Form
 - F208: Participant In-Center Log Sheet (non-dialytic Aspects of HD)
 - F218: Final MRI Scheduled

- F220: SF-36 (English and Spanish), v1
- F221: Beck Depression Inventory, v1
- F222: Cousineau Self-Perceived Burden Scale
- F223: Health Utilities Index 3 Form
- F224: central Interview Study Special Study Questions
- F225: MOS Sleep Scale
- F230: Feeling Thermometer Form
- F231: Modified Mini Mental Status
- F232: Trail Making B Form
- F233: Clinical Center Miscellaneous Questions
- F234: The FHN Combination Physical Function Tests Form
- F235: BDI Suicide Question Response
- F242: Single Frequency Bioelectrical Impedance (BIA) Assessment
- F250: Dialysis Session Before MRI
- F251: MRI Mailing Form
- F252A: Central MRI Data Entry Results
- F252B: Central MRI Data Entry Wall Motion Score
- F253: Daily Trial Central Heart Rate Variability Mailing Form
- F254: Daily Trial Central Holter Reading Facility Data Transmission Form
- F255: U.S. Biological Specimen Repository Mailing Form
- F256: International Biological Specimen Repository Mailing Form
- F257: Canadian Repository Collection Date Form
- F271: Access Used for Chronic Hemodialysis
- F273: Monthly Kinetic Modeling Form
- F274: Retrospective Kinetic Modeling Data
- F275: Attendance at In-Center Dialysis Sessions Form
- F276: Access Repair Procedure
- F277: Permanent Access Failure or Access Removal Form
- F278: New Access Placement
- F302: Clinical Center Hospitalization Notification Form
- F303: Clinical Center Detailed Hospitalization Form
- F305: Clinical Center Death Notification Form
- F306: Clinical center Detailed Death Form
- F307: Adverse Event Reporting Form
- F308: Serious Adverse Event Reporting Form
- F309: Planned Therapy Deviation
- F310: Detected Therapy Deviations
- F311: Daily Trial Central Holter Reading Facility Clinical Alerts Form
- F312: Central Cardiac MRI Clinical Alerts Form
- F313: Post Randomization Patient Transplant or Peritoneal Dialysis Form
- F400: Patient Transfer Form
- F401: Re-enrollment of Previously Enrolled Patient
- F404: Canadian Centers Vital Status
- F405: End of Trial Patient Status
- F406: Documentation of Consent for Repositories Form
- F503: Outcome Committee Death Review Form

- F600: Study Staff Information Form
 - F601: Clinical center Form
 - F602: Other Study Facilities Form (Lab, Holter)
 - F603: Dialysis Unit Details Form
 - F604: Cardiac MRI Facility
 - F605: Consortium Care
 - F606: Documentation of Local Laboratory Method, Instrument, and Normal Ranges
 - F700: Thirty Days After F12 Data
- Annotated_Forms_FHN_Daily.pdf – Annotated versions of the following forms:
 - Rand_Daily: FHN Daily Trial On-Line Randomization
 - F104
 - F105
 - F110
 - F112
 - F202
 - F203
 - F204
 - F205
 - F206
 - F207
 - F208
 - F220
 - F221
 - F222
 - F223
 - F224
 - F225
 - F230
 - F231
 - F232
 - F233
 - F234
 - F235
 - F242
 - F250
 - F251
 - F252A, B
 - F253
 - F254
 - F255
 - F256
 - F271
 - F273
 - F274
 - F275
 - F276
 - F277
 - F278
 - F302
 - F303
 - F306
 - F307
 - F308
 - F309
 - F310
 - F311
 - F312
 - F313
 - F404
 - F405
 - F406
 - F501
 - F503
 - F700

Data

The FHN Daily data directory contains the following subdirectories:

Data\Raw Data

The FHN Daily raw data directory contains the following files, and the following raw datasets in Windows-based SAS, v. 9 format:

- The following datasets correspond to the form with the same name:
 - f104_daily.sas7bdat
 - f105_daily.sas7bdat
 - f110_daily.sas7bdat
 - f112_daily.sas7bdat
 - f202_daily.sas7bdat
 - f203_daily.sas7bdat
 - f204_daily.sas7bdat
 - f205_daily.sas7bdat
 - f206_daily.sas7bdat
 - f207_daily.sas7bdat
 - f208_daily.sas7bdat
 - f220_daily.sas7bdat
 - f221_daily.sas7bdat
 - f222_daily.sas7bdat
 - f223_daily.sas7bdat
 - f224_daily.sas7bdat
 - f225_daily.sas7bdat
 - f230_daily.sas7bdat
 - f231_daily.sas7bdat
 - f232_daily.sas7bdat
 - f233_daily.sas7bdat
 - f234_daily.sas7bdat
 - f235_daily.sas7bdat
 - f242_daily.sas7bdat
 - f250_daily.sas7bdat
 - f251_daily.sas7bdat
 - f252_daily.sas7bdat
 - f253_daily.sas7bdat
 - f254_daily.sas7bdat
 - f255_daily.sas7bdat
 - f256_daily.sas7bdat
 - f271_daily.sas7bdat
 - f273_daily.sas7bdat
 - f274_daily.sas7bdat
 - f275_daily.sas7bdat
 - f276_daily.sas7bdat
 - f277_daily.sas7bdat
 - f278_daily.sas7bdat
 - f302_daily.sas7bdat
 - f303_daily.sas7bdat
 - f305_daily.sas7bdat
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 - f311_daily.sas7bdat
 - f312_daily.sas7bdat
 - f313_daily.sas7bdat
 - f404_daily.sas7bdat
 - f405_daily.sas7bdat
 - f406_daily.sas7bdat

- f501_daily.sas7bdat
- f503_daily.sas7bdat
- f700_daily.sas7bdat
- rand_daily.sas7bdat
- The following datasets are also included:
 - death_codes_daily.sas7bdat – Cause of death code and description corresponding to Form 306
 - dialyzer_daily.sas7bdat – Dialyzer information corresponding to Form 273
 - hosp_codes_daily.sas7bdat – Hospital codes corresponding to Form 303

Data\Raw Data\Contents

This subdirectory contains contents/frequencies of data sets in the Data\Raw Data directory.

Data\Analysis Data

The FHN Daily analysis data directory contains the following files, and the following datasets in Windows-based SAS, v. 9 format:

- analysis_monthly_d.sas7bdat – This analysis dataset contains 3387 observations, and has multiple records per patient, detailing laboratory results from each month they were enrolled in the study. Data includes blood flow, dialyzer flow, serum albumin and creatinine, blood pressure, weight gain, potassium, and iron.
- analysis_quarterly_d.sas7bdat – This analysis dataset contains 1225 observations, and has multiple records per patient, one for every four months they were enrolled in the study. Data includes lab results such as BMI, Beck Depression Inventory Score, medication use, serum albumin, weight gain, iron, and other laboratory and form results.
- acc_fails.sas7bdat – This analysis dataset contains 428 observations, and contains information about fistula, graft, and catheter use and failure.
- acc_repairs.sas7bdat – This analysis dataset contains 434 observations, and contains data about fistula, graft, and catheter use and repairs done to them.

Data\Analysis Data\Contents

This subdirectory contains contents/frequencies of data sets in the Data\Analysis Data directory.

DSIC

The FHN Daily Data Integrity Check (DSIC) directory contains:

- A report of an examination of the table1 (Chertow paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the FHN Daily data were compared to values recalculated from FHN Daily archived analysis datasets in the NIDDK repository.