

The FHN Nocturnal Study Data Archive

The FHN Nocturnal 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 Nocturnal Documents directory contains:

- PUB_LIST_September 2014.doc - Publications and presentations as of September 2014
- NocturnalProtocol_10.15.09_v3.3_archived_modifications.pdf – Most recent version of the FHN Nocturnal protocol
- /Documents/MOP - FHN Nocturnal Manual of Operations by chapters.
 - Chapter1_Protocol Changes.pdf
 - Chapter3_Nocturnal Study Overview.pdf
 - Chapter4_ReadytoRandomize.pdf
 - Chapter5_Guidelines for Study Coordinators.pdf
 - Chapter6_Computing and Data Entry.pdf
 - Chapter7_Cardiac MRI.pdf
 - Chapter8_Quality of Life.pdf
 - Chapter9_USRDS Data Flow.pdf
 - Chapter10_Comorbidty Assessment.pdf
 - Chapter11_Modified Mini Mental.pdf
 - Chapter12_Physical Functioning.pdf
 - Chapter13_Trail Making B.pdf
 - Chapter14_Feeling Thermometer.pdf
 - Chapter15_BIA.pdf
 - Chapter17_Omron Blood Pressure_archive.pdf
 - Chapter19_Kinetic Modeling Noct_archive.pdf
 - Chapter20_Standards of Care.pdf
 - Chapter21_Specimens for Local Labs.pdf
 - Chapter22_Specimens for NIDDK Repository_archive.pdf
 - Chapter23_Billing.pdf
 - Chapter24_Economic Analysis.pdf
 - Chapter25_Outcome Committee_archive.pdf
 - Chapter26_Publications Policies.pdf
 - Chapter27_Ancillary Studies.pdf

- Chapter28_Trial Talking Points for Investigators.pdf
- Chapter29_Certification and Quality Control.pdf
- MOP_TableOfContents.pdf

Forms

The FHN Nocturnal Forms directory contains (note that forms 220 (SF-36, v1), 221 (Beck Depression Inventory, v1), 223 (Health Utilities Index 3 Form), and 235 (BDI Suicide Question Response) were deleted due to copyright):

- Forms_TableOfContents.pdf – List of all forms used during the study
- Noct_Baseline_Visit_Schedule.pdf – List of the forms used during baseline
- Noct_FUP_Visit_Schedule.pdf – List of the forms from used during the follow-up period.
- /Forms/Blank: Blank versions of the following forms:
 - form100_noct – Nocturnal Trial Eligibility Confirmation (Screening) Form
 - form101_noct – Nocturnal Trial Home Suitability Form
 - form102_noct – Nocturnal Trial Patient Assessment Form
 - form103_noct – Nocturnal Trial Pre-Randomization Drop-out form
 - form104_noct – Co-Morbidity and Medical History Form
 - form105_noct – Baseline Demographics, Employment, and Income Form
 - form107_noct – Direct Patient Contact Form
 - form108_noct – U.S. Patient Future Linkage Form
 - form201_noct – Nocturnal Trial v2.1 Results of Training Form
 - form202_noct – Amputation Form
 - form203_noct – Monthly IV Iron Therapy
 - form204_noct – Injectable Medications Form
 - form205_noct – Medications and Supplements Form
 - form206_noct – Residual Renal Functions
 - form207_noct – Biochemistry Laboratory Data Form
 - form208_noct – Participant In-Center Log Sheet (Non-dialytic Aspects of HD)
 - form209_noct – Participant Dialyzing at Home Log Sheet (Non-dialytic Aspects of HD)
 - form211_noct – Nocturnal Trial v3.0 Results of Baseline Home Training Form
 - form212_noct – Nocturnal Trial Patient’s Water Quality Monitoring Form
 - form213_noct – Nocturnal Trial Home BP Patient Worksheet Request Form
 - form214_noct – Patient Home BP Collection Worksheet (Sample)
 - form215_noct – Nocturnal Study Staff Home BP Form
 - form216_noct – Nocturnal Trial v3.0 Results of Home Hemodialysis Training
 - form218_noct – Final MRI Scheduled
 - form222_noct – Cousineau Self-Perceived Burden Scale
 - form224_noct – Central Interview Study Special Study Questions
 - form225_noct – MOS Sleep Scale
 - form230_noct – Feeling Thermometer Form
 - form231_noct – Modified Mini Mental Status
 - form232_noct – Trail Making B Form
 - form233_noct – Clinical Center Miscellaneous Questions

- form234_noct – The FHN Combination Physical Function Tests Form
- form241_noct – Patient Main Meal Questions
- form242_noct – Single Frequency Bioelectrical Impedance (BIA) Assessment
- form250_noct – Dialysis Session Before MRI
- form251_noct – MRI Mailing Form
- form252A_noct – Central MRI Data Entry Results
- form252B_noct – Central MRI Data Entry Wall Motion Score
- form255_noct – U.S. Biological Specimen Repository Mailing Form
- form256_noct – International Biological Specimen Repository Mailing Form
- form257_noct – Canadian Repository Collection Data Form
- form260_noct – Nocturnal Trial Actual Costs of Home Modifications
- form271_noct – Access Used for Chronic Hemodialysis
- form273_noct – Monthly Kinetic Modeling Form
- form274_noct – Retrospective Kinetic Modeling Data
- form275_noct – Attendance at In-Center Dialysis Sessions Form
- form276_noct – Access Repair Procedure
- form277_noct – Permanent Access Failure or Access Removal Form
- form278_noct – New Access Placement
- form279_noct – Completion of Nocturnal v3.0 Home Dialysis Sessions
- form302_noct – Clinical Center Hospitalization Notification Form
- form303_noct – Clinical Center Detailed Hospitalization Form
- form305_noct – Clinical Center Death Notification Form
- form306_noct – Clinical Center Detailed Death Form
- form307_noct – Adverse Event Reporting Form
- form308_noct – Serious Adverse Event Reporting Form
- form309_noct – Planned Therapy Deviation
- form310_noct – Detected Therapy Deviations
- form312_noct – Central Cardiac MRI Clinical Alerts Form
- form313_noct – Post Randomization Patient Transplant or Peritoneal Dialysis Form
- form400_noct – Patient Transfer Form
- form404_noct – Canadian Centers Vital Status
- form406_noct – Documentation of Consent for Repositories Form
- form501_noct – Outcome Committee Hospitalization Review Form
- form503_noct – Outcome Committee Death Review Form
- form600_noct – Study Staff Information Form
- form601_noct – Clinical Center Form
- form602_noct – Other Study Facilities Form (Lab, Holter)
- form603_noct – Dialysis Unit Details Form
- form604_noct – Cardiac MRI Facility
- form605_noct – Consortium Core
- form606_noct – Documentation of Local Laboratory, Method, Instrument, and Normal Ranges
- form700_noct – Thirty Days after F12 Data
- formRAND_NOCT – FHN Nocturnal Trial On-Line Randomization Form
- /Forms/Annotated: Annotated version of the following forms:

- f100_noct
- f101_noct
- f102_noct
- f103_noct
- f104_noct
- f105_noct
- f201_noct
- f202_noct
- f203_noct
- f204_noct
- f205_noct
- f206_noct
- f207_noct
- f208_noct
- f209_noct
- f211_noct
- f212_noct
- f216_noct
- f222_noct
- f224_noct
- f225_noct
- f230_noct
- f231_noct
- f232_noct
- f233_noct
- f234_noct
- f242_noct
- f250_noct
- f251_noct
- f252_A_B_noct
- f255_noct
- f256_noct
- f260_noct
- f271_noct
- f274_noct
- f275_noct
- f276_noct
- f277_noct
- f278_noct
- f279_noct
- f302_noct
- f303_noct
- f305_noct
- f306_noct
- f307_noct
- f308_noct
- f309_noct
- f310_noct
- f311_noct
- f312_noct
- f313_noct
- f404_noct
- f405_noct
- f406_noct
- f501_noct
- f503_noct
- f700_noct
- noct_randomization

Data

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

- The following datasets correspond to the form with the same name:

- f100_noct.sas7bdat
- f101_noct.sas7bdat
- f102_noct.sas7bdat
- f103_noct.sas7bdat
- f104_noct.sas7bdat
- f105_noct.sas7bdat
- f201_noct.sas7bdat
- f202_noct.sas7bdat
- f203_noct.sas7bdat
- f204_noct.sas7bdat
- f205_noct.sas7bdat
- f206_noct.sas7bdat
- f207_noct.sas7bdat
- f208_noct.sas7bdat

- f209_noct.sas7bdat
- f211_noct.sas7bdat
- f212_noct.sas7bdat
- f216_noct.sas7bdat
- f220_noct.sas7bdat
- f221_noct.sas7bdat
- f222_noct.sas7bdat
- f223_noct.sas7bdat
- f224_noct.sas7bdat
- f225_noct.sas7bdat
- f230_noct.sas7bdat
- f231_noct.sas7bdat
- f232_noct.sas7bdat
- f233_noct.sas7bdat
- f234_noct.sas7bdat
- f235_noct.sas7bdat
- f241_noct.sas7bdat
- f242_noct.sas7bdat
- f250_noct.sas7bdat
- f251_noct.sas7bdat
- f252_noct.sas7bdat
- f255_noct.sas7bdat
- f256_noct.sas7bdat
- f260_noct.sas7bdat
- f271_noct.sas7bdat
- f273_noct.sas7bdat
- f274_noct.sas7bdat
- f275_noct.sas7bdat
- f276_noct.sas7bdat
- f277_noct.sas7bdat
- f278_noct.sas7bdat
- f279_noct.sas7bdat
- f302_noct.sas7bdat
- f303_noct.sas7bdat
- f305_noct.sas7bdat
- f306_noct.sas7bdat
- f307_noct.sas7bdat
- f308_noct.sas7bdat
- f309_noct.sas7bdat
- f310_noct.sas7bdat
- f312_noct.sas7bdat
- f313_noct.sas7bdat
- f404_noct.sas7bdat
- f405_noct.sas7bdat
- f406_noct.sas7bdat
- f501_noct.sas7bdat
- f503_noct.sas7bdat
- f602_noct.sas7bdat
- f606_noct.sas7bdat
- f700_noct.sas7bdat
- hosp_codes_noct.sas7bdat
- rand_noct.sas7bdat

- The following dataset is also included:
 - kinetic.sas7bdat – Variables from kinetic modeling sessions

- /Data/Contents: Contents of the following data sets in PDF format.

- | | |
|--------|--------|
| • F100 | • F202 |
| • F101 | • F203 |
| • F102 | • F204 |
| • F103 | • F205 |
| • F104 | • F206 |
| • F105 | • F207 |
| • F201 | • F208 |

- F209
- F211
- F212
- F216
- F220
- F221
- F222
- F223
- F224
- F225
- F230
- F231
- F232
- F233
- F234
- F235
- F241
- F242
- F250
- F251
- F252
- F255
- F256
- F260
- F271
- F273
- F273_Dialyzer
- F274
- F275
- F276
- F277
- F278
- F279
- F302
- F303
- F303_Hospital_Codes
- F305
- F305_306_Death_Codes
- F306
- F306_Death_Codes
- F307
- F308
- F309
- F310
- F312
- F313
- F404
- F405
- F406
- F501
- F503
- F700
- Randomization

DSIC

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

- FHN_Nocturnal_DSIC.pdf – A report of an examination of the FHN Nocturnal datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replication Table 1, Table 2, Table 3, and Table 4 from the paper ‘The effects of frequent nocturnal home hemodialysis: the Frequent Hemodialysis Network Nocturnal Trial’ by Rocco et al. Published results from the FHN Nocturnal data were compared to values recalculated from FHN Nocturnal archived datasets in the NIDDK repository.