

The PROBE Study Data Archive

The Prospective Database of Infants with Cholestasis (PROBE) Archive contains the Protocol, Manual of Operations, Forms, and Study Data.

Archive files are organized into the following directories:

- Data
- Documentation
- DSIC
- Forms
- SAS Programs

Documentation

The PROBE Documentation directory contains:

- key publications.docx – A listing and description of three major publications published by the PROBE study
- MOO PROBE V2.1 (1).pdf – Manual of Operations for the PROBE study
- probe_amend6.pdf – Protocol (Version 7, Amendment 6) for the PROBE study
- PUBLICATIONS.docx – Listing of all publications from the PROBE study
- Final_MOO PROBE V2.2 Clean Copy .pdf
- Older BA Neuro Manuscript Codebook.docx
- PROBE Publications.docx
- PROBE_Version 08 Amendment 7_FINAL_120617 clean(003).pdf

Forms

The PROBE Forms directory contains the following:

- 01 Eligibility.pdf – Contains data on medical history necessary to determine eligibility for the PROBE study, as well as information on informed consent
- 02A Subject Demographics.pdf – Contains information on gender, race, and ethnicity
- 03 Initial History.pdf – Contains information on all prior visits the child has had with health professionals, as well as whether the child has had white or pale stools, and for how long
- 07 Physical Exam.pdf – Contains data on physical measurements (weight, height, etc.), skin exam, facial features exam, eye exam, liver exam, spleen exam, and anomalies and abnormalities
- 08 Labs Intial Pre-lap.pdf – Contains data on lab results including bilirubin, AST, ALT, Alkaline phosphatase, Albumin, protein, GGTP, Vitamins, hemoglobin, WBC, platelets, sodium, potassium, glucose, creatinine, calcium, phosphorus, cholesterol, etc.
- 11_Surgery.pdf – Contains data on any anomalies noted during surgery, liver appearance, gallbladder fluid, common bile duct appearance, patent observations, diagnosis and classification, drainage procedures, complications, and liver biopsy
- 14 Diagnosis.pdf – Contains data on primary diagnosis at discharge, as well as later diagnoses
- 25N Liver Transplant.pdf – Contains data on any liver transplants done, including lab results, donor type, complications, and UNOS status
- 27C Biliary_Ultrasound.pdf – Contains data on liver results, portal vein results, spleen results, and any other findings

- 29 Change in Diagnosis.pdf – Contains data on primary diagnosis, if changed, as well as any other later diagnoses
- Form 35 Final Status PROBE.pdf – Contains data on why a subjects is leaving the study, or changing sites, including reason for withdrawal or loss to follow-up, and cause of death
- 21C_Bayley II_v04_2006_12_01_Annotated.doc
- 25N Liver Transplant.pdf
- BSID Bayley III.pdf
- Family Demographics PROBE.pdf
- Form 03C Anomalies PROBE.pdf
- Form 07 Physical Exam PROBE.pdf
- Form 08 Labs Initial Pre-lap PROBE.pdf
- Form 08 Labs Initial Presentation PROBE.pdf
- Form 11 Surgery PROBE.pdf
- Form 12 Hospital Discharge PROBE.pdf
- Form 13 Discharge Medications PROBE.pdf
- Form 20 Physical Exam FU PROBE.pdf
- Form 22 FU Diet_Meds PROBE.pdf
- Form 23 FU Labs PROBE.pdf
- Form 25C Ascending Cholangitis.pdf
- Form 25D Ascites.pdf
- Form 25F GI Bleed.pdf
- Form 25H Coagulopathy.pdf
- Form 26 FU Surgery.pdf
- Liver Stiffness Measurement FORCE.pdf
- Wechsler Intelligence Scale for Children.pdf
- WPPSI Wechsler Preschool and Primary Scale of Intelligence.pdf

Data

The PROBE Data directory contains:

- Discriminate_ba.sas7bdat – Analysis dataset for a PROBE publication, containing key variables, such as bilirubin, AST, ALT, race, gender, acholic stools, weight, height, patent observations, and analytic group
- Data Dictionary for SAS Dataset Predictors.docx – Contents listing for discriminate_ba.sas7bdat dataset
- analysis_Data_Derivation.docx
- analysis.sas7bdat
- baneuro_formats_14mar19.sas7bcat
- baneuro_raw_14mar19.sas7bdat
- surgery_dataset.sas7bdat
- Surgery Manuscript Data Specifications.docx

DSIC

- PROBE_Bilirubin_integrity_check_analysis.doc
- probe_integrity_check_02152017.doc
- PROBE_integrity_check_analysis_JSquires_V3.pdf
- PROBE_integrity_check_analysis_Superina.doc

SAS Programs

- SAS_alloutput_16jul2019_NIDDK.pdf