

## STUDIES OF PEDIATRIC LIVER TRANSPLANT (SPLIT)

Studies of Pediatric Liver Transplant (SPLIT) is a collaborative research effort between transplant centers in the U.S. and Canada that was organized in 1995 to collect and analyze information required to advance the science of pediatric liver transplantation. Participation in this registry is voluntary. A Data Coordinating Center, located at The EMMES Corporation, is responsible for data collection and analyses. In 2004, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) became the sponsor of SPLIT. SPLIT data archived in the NIDDK repository include study information on any participant enrolled under the NIDDK grant period and for participants that have any follow-up after the start of the grant period even if enrolled prior to the grant period.

The files in the archive are organized into the following directories:

1. Documentation
2. Forms
3. Data
4. Dataset Integrity Check (DSIC)

### 1. Documentation Directory

The SPLIT Documentation Directory contains:

- A brief description of the SPLIT registry, *SPLIT General Description.pdf*
- SPLIT protocol, *SPLIT\_protocol 2.1.doc*
- Bibliographies of all SPLIT publications, *SPLIT\_Bibliography.doc*, and a listing of publications supported by NIDDK, *Publications Grant Supported.doc*

### 2. Forms Directory

The SPLIT Forms Directory contains 23 annotated data collection forms (.pdf) used in the SPLIT studies. A brief description of each form is provided below in Table 1. In addition, a description of scheduled and non-scheduled assessments and instructions for completing each of the data collection the forms are provided, *Forms Instructions 3.0.doc*.

Scheduled assessments occur at 1) pretransplant, 2) transplant, and 3) EBV/LPD (Epstein Barr Virus/ diagnosis).

### 3. Data Directory

The SPLIT Data Directory contains:

- 23 SAS data files (\*.sas7bdat) corresponding to 22 of the data collection forms. The enrollment form, enr.sas7bdat, included only the date of enrollment and was not included in the repository. The data file, ecsplita.sas7bdat, is not associated with a study data form but provides the age at listing evaluation (in days).
- Proc Format subdirectory which includes SAS proc format statements for each of the 23 SAS data files called "applyform\_datasetName.SAS". All the formats are defined in malformat.sas. Variable labels are defined in names.sas.
- The file SPLIT Data Contents.rtf provides an alphabetic list of variables and attributes for each dataset using the SAS Contents procedure.

Table 1 provides a listing of the study data files and corresponding case report forms.

**Table 1. Study data and forms**

Form Name	Description	SAS Dataset /Form Code
ADHD Rating Scale IV	Pre-transplant: child behavior	ADH
Autoimmune Hepatitis	Pre-transplant: AIH type	AIH
Demographics	Pre-transplant: Demographics, primary liver disease dx	DEM
Death	Pre-transplant: death	DTH
School Attendance and Performance Survey	1 <sup>st</sup> transplant sequence:	EDU
Symptomatic EBV/LPD Evaluation	3 <sup>rd</sup> EBV/LPD sequence:	ELE
Symptomatic EBV/LPD Follow-up	3 <sup>rd</sup> EBV/LPD sequence:	ELF
Enrollment	Enrollment date (date of transplant)	ENR*
Family History of Heart Disease and Diabetes	1 <sup>st</sup> transplant sequence:	HDD
Lost to Follow-up/Exit	Pre-transplant: LFU/early exit	LFE
Long-term Post-transplant Follow-up	1 <sup>st</sup> transplant sequence: assessments, complications since last visit	LTF
Long-term Medications	1 <sup>st</sup> transplant sequence: immunosuppressants, antivirals, concomitant meds,	LTM
Primary Sclerosing Cholangitis	Pre-transplant: pre- and post-first transplant information	PSC
Pre-transplant Evaluation	Pre-transplant: data at transplant listing	PTE
Pre-transplant Follow-up	Pre-transplant: Every 6 mos (up to 2 yr), then annually until transplant, exit, LFU, or death	PTF
Rejection	1 <sup>st</sup> transplant sequence	REJ
Re-transplant Evaluation	1 <sup>st</sup> transplant sequence: data at re-transplant listing	RTE
Status 1 Listing	Pre-transplant: labs, symptoms at status 1 listing	S1L
Status 1 Outcome	Pre-transplant: labs, events at removal from status 1 listing	S1O
Transplant Early Follow-up	1 <sup>st</sup> transplant sequence: Hospitalization, complications, chemistries; completed 30 days post-transplant	TPF
Transplant Medications	1 <sup>st</sup> transplant sequence: Therapies, medications received within first 30 days of transplant	TPI
Transplant Baseline	1 <sup>st</sup> transplant sequence: Demographic and clinical data w/in 48 hrs of transplant	TPP
Transplant Surgical	1 <sup>st</sup> transplant sequence: Anastomosis,	TPS

	closure dates at time of transplant; completed by attending surgeon	
na	Age at listing evaluation	ECSPLITA

\* The enrollment form, enr.sas7bdat, included only the date of enrollment and was not included in the repository. The SAS data ecsplita.sas7bdat is not associated with a study data collection form.

#### **4. Data Integrity Check**

The SPLIT Data Integrity Check directory contains a report based on an examination of the data in the repository by statisticians and quality control specialists at the Repository. Data were checked for completeness, consistency, and usability. The published data from the study (Gilmour et al, School outcomes for children registered in the Studies for Pediatric Transplant (SPLIT) consortium, 2010, in *Liver Transplantation*) were compared to values recalculated from the SPLIT data in the NIDDK repository.