

SPLIT Operations Manual

2023

Executive Committee and Council



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Abbreviations:

Multi-D- Multi-Disciplinary Committee
 COI- Conflict of Interest
 CRF- Case Report Forms
 DCC- Data Coordinating Center
 EC- Executive Committee
 MAL- Medical At-Large Physician Liaison
 MYM- Mid-year Meeting
 PCO- Planning Conference Organizer
 PFEP- Patient and Family Engaged Partners Committee
 PI- Principal Investigator
 QICC- Quality Improvement Clinical Care Committee
 RFA- Request for Applications
 RFP- Request for Proposals
 ROC- Registry Operations Committee
 RSM- Registry Site Member
 SAL- Surgeon At-Large Physician Liaison
 SIM- SPLIT Individual Member
 SPLIT- Society of Pediatric Liver Transplant, Inc.
 TTS- The Transplantation Society
 TSM- The Transplant Society Administrative Liaison
 VP- Vice-President

SPLIT Operations Manual

This manual provides SPLIT members and stakeholders with a practical guide for how SPLIT accomplishes its mission. This document supplements the [SPLIT By-Laws](#) [See the SPLIT By-Laws in the Administrative Folder]. In the event of any discrepancy, the By-Laws are to be used as the final arbiter of action.

About SPLIT

SPLIT is a community of pediatric transplant surgeons, hepatologists, nurse and research coordinators, and allied health professionals across the United States and Canada working to advance knowledge in pediatric liver transplantation. The Studies of Pediatric Liver Transplantation was started in 1995 and has evolved from a voluntary research registry into a multifaceted organization focused on research, education, patient advocacy, and improving the quality and quantity of life for children receiving liver transplantation. The organization has continued to grow in scope and membership, but remains focused on the singular purpose of improving the lives of children with ESLD through liver transplantation, utilizing a robust data registry as the cornerstone for the SPLIT mission. In 2018, SPLIT incorporated under the new name, **The Society of Pediatric Liver Transplantation, Inc.**, and has become an official non-profit 501©(3) tax-exempt subsection of the Transplantation Society (TTS).

Mission

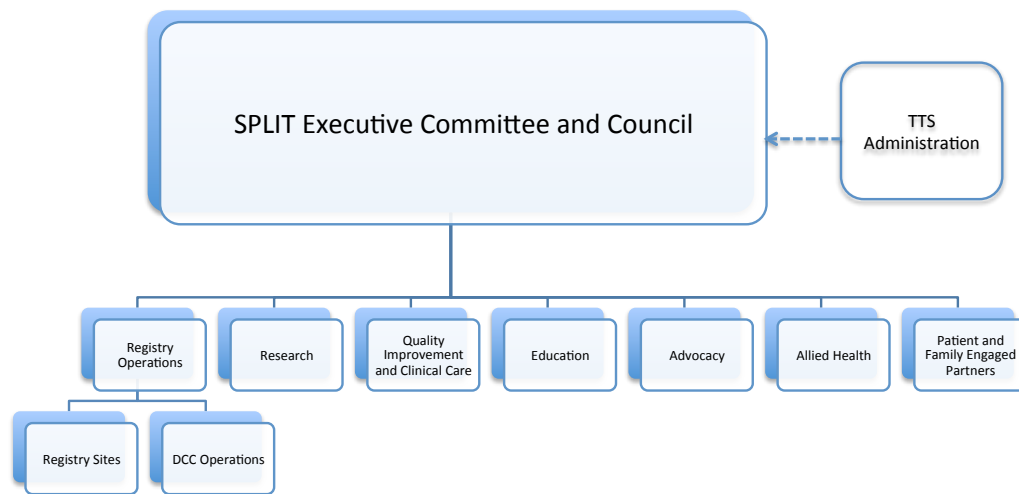
SPLIT's mission is to improve outcomes in children receiving liver transplantation through research, improving care, training and mentoring, and supporting children and families.

This mission is accomplished by:

1. Gaining new knowledge through observational and translational research, and clinical trials.
2. Leveraging the collective data from the SPLIT Registry
3. Improving care delivery by application of new knowledge and by reducing variation in care where

identification and dissemination of standardized processes lead to best practices.

4. Training and mentoring junior physicians, surgeons, multi disciplinary professionals, and clinical/research coordinators.
5. Advocating for children who require or have received a liver transplant.



SPLIT, Inc. Organizational Structure

Figure 1. SPLIT, Inc. Organizational Structure. The Executive Committee is composed of the President, President-Elect, Past-President, Secretary, Treasurer, a TTS liaison, and a data coordinating center (DCC) representative. The Council is composed of the Executive Committee, the Committee Chairs, and the Medical and Surgical At-Large Physicians.

The Transplantation Society (TTS)

This section describes the working relationship between SPLIT and the Transplantation Society (TTS), and educates the SPLIT membership on the TTS scope of facilitating the SPLIT mission.

TTS Vision Statement

"TTS will provide the focus for global leadership in transplantation."

TTS Role and Service

The TTS provides management and support services to SPLIT in:

1. Financial accounting and reporting
2. Individual SPLIT Membership
3. Website and communications technologies
4. Administration
5. Annual and Council meetings

Financial Accounting and Reporting

TTS holds and manages SPLIT funds in a separate SPLIT bank account, keeping deposits and investment funds separate from other TTS subsection accounts.

TTS maintains complete and proper accounting of SPLIT funds, investments, and provides quarterly reports to the Executive Committee (EC) to facilitate strategic initiatives and annual budgets.

TTS is authorized to reimburse invoicing individuals or organizations that have been approved by the EC or Council. TTS exercises reasonable judgement in paying any such invoices and affirms authorization by the SPLIT EC or Council when appropriate. TTS will follow SPLIT's outlined signing authority policy [Administrative Folder], which indicates the approvals required for payment of all expenses.

TTS organization, its councillors, directors, officers or employees have no liability arising from any investment loss incurred by SPLIT. Unless such loss was the result of fraud or theft carried out by a person whose activities or functions render TTS liable by law.

SPLIT and TTS Membership

TTS will maintain an up-to-date database with relevant SPLIT and dual SPLIT-TTS individual membership information. TTS will use all reasonable measures to ensure that all such membership information is kept confidential in accordance with applicable privacy laws. TTS will only disclose information consented to by the member, and only release information to persons within SPLIT or TTS in the normal reasonable course of activities.

SPLIT individual membership does not include membership in TTS, nor is TTS membership required as a condition of individual SPLIT membership. TTS membership is encouraged to promote full TTS service offering benefits. TTS has no obligation to SPLIT in the collection of SPLIT individual or Registry Site Member dues, and will not enforce any sanctions arising from non-payment.

Website and Communications Technologies

TTS owns exclusive rights to the website (www.tts.org) including the design and visual concept. As a subsection benefit, TTS permits a SPLIT-specific tab-linked site use of the website design and visual concept. TTS will manage the operation and relevant material content updates as provided by SPLIT. SPLIT is solely responsible for the Site content accuracy.

SPLIT bears exclusive liability for its tab-specific content, and TTS retains the right to remove any inappropriate or libellous material from inclusion on the SPLIT Site. In the event of any such inappropriate content being removed by TTS, written notification will be sent to the SPLIT EC.

All documents, text, photographs, videos, pictures, animation, sound recordings, and all other works of authorship provided by SPLIT for inclusion on the SPLIT Site, together with all images, likenesses and other characteristics contained therein remain the property of SPLIT and its licensors.

TTS will use all reasonable efforts to ensure that in hosting the SPLIT website, any third party will be able to access the SPLIT tab at all times. In the event of a website defect, TTS will correct the problem as soon as possible.

Nothing in the TTS-SPLIT relationship assumes any rights to use of trademark, logo, domain name or other intellectual property without prior written consent.

Administration

TTS supports the EC, Council, and designated committees by:

1. Maintaining Committee rosters and meeting attendance.
2. Archiving any conflicts of interest (COI) [[COI Policy-Administrative Folder](#)] for the Council.
3. Setting conference calls and circulating agendas.
4. Tracking committee member participation.
5. Intake, distribution, and archiving SPLIT project proposals.

Annual Meeting Support

TTS provides administrative support for the Council Meeting at the Annual meeting. As the planning conference organizer (PCO), TTS may also provide meeting support for other aspects of the meetings including:

1. Identifying a cost-effective venue for meetings
2. Administrative support to the host center and Education Committee
3. On-site meeting registration and member sign-ups

Emmes

The Emmes Company, LLC is a Contract Research Organization (CRO) based in Rockville, MD that serves as the SPLIT Registry Data Coordinating Center (DCC). Emmes helped found SPLIT in 1995 and has since provided data management support.

Roles and Services

As the SPLIT DCC, Emmes provides the following services to the SPLIT Registry:

- Registry Operations Committee support
- Proposal study design, review, and project management
- Registry Site membership and roster management
- Invoicing and ROC budgeting
- Member Site Regulatory oversight
- Data entry training
- Data collection, cleaning, freezes, and analysis
- Registry Site data management support
- Study materials
- Annual reports
- Benchmarking tool maintenance and reports
- Registry operations website management

Registry Operations Committee Support

The DCC is responsible for helping manage and support the activities of the Registry Operations Committee (ROC) including managing the leadership election process, committee membership, Registry strategy input, and supporting ROC calls.

Registry Site Membership and ROC Roster

"SPLIT Registry Site members (RSM's)" "transplant center members," and "centers" are synonymous terms used to describe transplant centers that have paid annual membership dues, consented patients, and submitted data to the Registry.

Emmes, in collaboration with the ROC, manages the Registry Site membership including onboarding new sites and monitoring RSM data entry performance. Emmes and the ROC maintain a roster of Registry Site staff and roles.

Invoicing and Budgeting

The ROC (with support from Emmes) will invoice new and participating Registry Sites on an annual basis for the upcoming calendar year unless otherwise arranged. Registry Site payments will be considered delinquent on December 1, to allow time for end-of-year budget adjustments and tax preparation. The ROC and Emmes will provide semi-annual status reports on RSM payments, and inform the EC of pending payments not received by the late payment deadline. The ROC Chair will generate notices to Registry Sites (with cc: to the EC) requesting late payment. The ROC and Emmes will generate semi-annual budget reporting to the EC. (See the Registry Operations Section- Registry Site Annual Dues)

Registry Site Regulatory Oversight

Emmes ensures all participating RSM's have met the Registry Site regulatory requirements including ethics board approvals, staff trainings, and site certifications.

Data Collection, Cleaning, and Data Analysis

Emmes utilizes its proprietary Clinical Data Management System (CDMS), Advantage eClinical™ to collect data from participating Registry Sites. Emmes supports the Sites in this activity including training RSM staff and answering Site questions. Emmes generates and distributes data queries on a regular basis to help ensure the Registry data is complete and accurate, and maintains data set analysis for reporting upon request. [See Registry Operations Section below on Submitting Data Requests] The ROC produces data quality summary reports to facilitate data quality improvement.

SPLIT Registry Site Study Materials

Emmes creates and maintains study materials for the RSM's including the protocols, informed consent templates, Registry procedures, case report forms (CRF's), CDMS and forms instructions, data dictionary, and study logs.

Data Reporting

Emmes creates and maintains various summary and outcome metric reports which are posted on the website to be used by the ROC and RSM's. This also includes the benchmarking reports used to query RSM performance compared to the SPLIT cohort.

Website Management

Emmes develops and maintains the Registry website (**splitdcc.org**) which serves as a repository for all Registry-related study materials, reports, rosters, and call information. Only listed staff at a RSM will have access to the Registry website.

On-Line Benchmarking Tool

The on-line **benchmarking** (BM) platform, conceptual framework, and content was designed by Emmes in collaboration with the QICC and ROC for use on the SPLIT Registry website (www.splitdcc.org). The BM tool provides a "snapshot" view of the logged-in member's Registry Site performance in a filtered outcome compared to the performance of the U.S. Registry Sites that meet the minimum data inclusion requirements. The BM tool is the sole property of SPLIT, Inc. and is intended to be a survey of filtered measures. The data contained within the BM tool is **not** designed for manuscript quality data analysis reporting, and this use is strongly discouraged. Any presentation of BM tool data beyond the internal registry site use requires review via the Content Review process below. [See the Research Committee Section on Content Review]

Membership

SPLIT Individual Membership

SPLIT individual membership will be open to any physician, allied health professional, or trainee who is interested and/or involved in the field of pediatric liver transplantation.

To become a SPLIT individual member (SIM), interested professionals will complete the online application and [Ethics Statement](#) [Administrative Folder] via the TTS website. The EC will review and approve SPLIT individual membership applications for demonstrated experience and interest in pediatric liver transplantation. Accepted individual members will be notified and welcomed by the TTS

administrative membership staff. All SIM's in good standing will be eligible to serve on SPLIT committees and vote in elections. Membership in TTS is not mandatory to become a SIM, but is encouraged.

SIM's are considered to be in "**good standing**" if membership dues are not outstanding beyond one year. The membership levels as described in the SPLIT by-laws are Full Physician, Allied Health, Trainee, and Honorary. At the discretion of the Council, "Honorary membership" status is reserved for distinguished individuals who have demonstrated major contributions to pediatric liver transplantation.

Individual TTS Membership

To become a member of the Transplantation Society (TTS), applicants must complete and submit the application available on the TTS website, (www.tts.org) and pay the appropriate TTS membership dues.

SPLIT Registry Site Membership

Transplant Centers wishing to join the SPLIT Registry must submit the completed application available on the DCC (Emmes) website (www.splitdcc.org). The ROC will review applications, present perspective Registry Site applicants to the EC, and notify Sites. RSM's will pay annual dues, be eligible to receive the SPLIT Annual Report, and have access to Registry and BM data. RSM's are expected to remain up to date on the annual participation dues to continue to receive uninterrupted DCC service. It is expected that the RSM Principal Investigator (PI) will also be a SIM in good standing. [See Article II: Membership of the SPLIT By-Laws and the Registry Operations Committee Section].

SPLIT Committee Purpose and Structure

Executive Committee

The Executive Committee (EC) is comprised of the President, Vice-President (VP or President-Elect), Past President, Treasurer, Secretary, a DCC Representative and a TTS Section Manager(TSM).

The EC plans the SPLIT strategic vision as executed by the Council and Committee Chairs, and serves the interests of SPLIT members and stakeholders.

The EC also oversees day-to-day SPLIT operations as well as generates, approves, and executes all budgets and financial actions.

Issues requiring a vote will be decided by simple majority vote in person, by email, or by phone call of the EC members. The TSM and DCC Representative are non-voting EC members.

SPLIT Council

The SPLIT Council is comprised of the EC, the Committee Chairs, and two At-Large (Ad Hoc) physician members. [See Article IV: Council, of the SPLIT By-Laws] The Council is responsible for the overall management of SPLIT, including defining the mission, monitoring adherence to mission, strategic planning, fiscal management, COI's, and election of the EC officers. As annual budget allows, the Council may announce a RFP ([Request for Proposals Form](#)) [Administrative Folder] to stimulate and support innovative initiatives. [See Section below- Council Requests for Proposals and Applications] All Council members will adhere to the [Conflicts of Interest Policy](#) [Administrative Folder] and signed disclosures will be archived by the TSM. No SPLIT Council member will receive compensation for Council service. All Council members will follow standards of conduct that are ethical, honest, and above reproach. Any Council member believing in good faith that another Council member is engaging in dishonest, illegal, or fraudulent behavior that would damage the reputation of SPLIT, should notify the EC for further evaluation without any concerns for retaliation.

Leadership Succession

The Council nominates and elects the President, VP, Secretary, and Treasurer from the Council membership. The premise being that participation and demonstrated leadership on a committee leads to Committee Chairs and participation on the Council. Demonstrated leadership and knowledge of the strategic direction of SPLIT on the Council leads to the opportunity to be nominated for Council leadership and continuity of leadership succession planning. Once nominated, the VP, Secretary, and Treasurer will each be elected by a vote of the general SPLIT members in good standing, to serve a two-year term. The VP will assume the role as President and the President will assume the position of Past President at the end of their

respective two-year terms. All candidates for a committee leadership position must complete a **SPLIT Candidate Overview** form [Administrative Folder], which is then distributed to the committee prior to voting, when a vote is required. Results are determined by a simple majority of committee members. In the event that no Council member wishes to be nominated for an EC role, the existing Council members will conduct a general call for nominations from the SPLIT individual membership. The respective job descriptions for the EC officers and Council members are included in the **SPLIT By-Laws**-Article IV. Each respective SPLIT committee elects their Chair and Vice-Chair from their respective committee membership. Each Chair will serve a three-year term. The Vice-Chair will assume the role as committee Chair at the end of three years following the Annual meeting. Results are determined by a simple majority of committee members who vote within the specified timeframe. [See Figure 2. and the distinctions in Leadership Succession Planning for the Education and PFEP Committees in those respective manual sections]

SPLIT Council Role	Term Limit	Succession Plan
President	2 years	Becomes Past President
Vice-President (President-Elect)	2 years	Becomes President
Past President	2 years	Succeeded by President
Treasurer	2 years	Succeeded by new Electee
Secretary	2 years	Succeeded by new Electee
Registry Operations Committee (ROC) Physician Chair	3 years	Succeeded by Vice-Chair
ROC Coordinator Chair	3 years	Succeeded by Vice-Chair
Research Committee Chair	3 years	Succeeded by Vice-Chair
Quality Improvement Clinical Care Committee Chair (QICC)	3 years	Succeeded by Vice-Chair
Education Committee Chair	3 years	Succeeded by Vice-Chair
Advocacy Committee	3 years	Succeeded by Vice-Chair
Allied Health Professionals Committee Chair (AHP)	3 years	Succeeded by Vice-Chair
Patient and Family Engaged Partners Committee Chair (PFEP)	3 years	TBD
Medical Physician-at-large (MAL)	3 years	Succeeded by new Electee
Surgeon-at-large (SAL)	3 years	Succeeded by new Electee
DCC Representative	No Limit	
TSM Representative	No Limit	

Figure 2. SPLIT Council Succession Plan

At-Large (Ad Hoc) Physician/Surgeon

Any physician, who is a SIM in good standing, is eligible to serve as an At-Large Council member. The Medical (MAL) and Surgical At-Large (SAL) Council members represent the contemporary pediatric liver transplant community clinical and research interests in addition to focused SPLIT Committees. These members shall be nominated and elected from the SPLIT individual membership and will serve a 3-year term on the SPLIT Council as a voting member. The RSM PI's and the SIM's elect the MAL and SAL members. The PI's cast only one vote for the MAL and SAL positions, respectively.

Conference Calls/Meetings

Council Members meet by conference call on a monthly basis. The TSM works with the President and VP to determine agenda items prior to each call. Call minutes are taken and archived by the TSM.

The Council meets in-person approximately twice a year—once during the Fall annual meeting, and again typically in the Spring, at the Mid-Year Meeting (MYM) as needed.

Voting

Council members have a single vote for all issues requiring a vote call. (i.e. even for Council members serving as site PI's or in multiple Council capacities). Approval is determined by a simple majority of the quorum of committee members. A quorum will be defined as a simple majority of council members in attendance unless the law requires more representative members. The TSM and The DCC Representative are non-voting Council members.

Council Requests for Proposals and Applications

As strategic goals and annual budget direct, Council under the guide of a 501(c)3 incorporation, will periodically issue a Request for Proposal Applications (RFA) for project grant funding to leverage society activities, including research, quality improvement, education, and advocacy. Announcement of an upcoming RFA will be provided to all SIM's in good standing with adequate time for application preparation and transparent due dates and evaluation timelines. Applications will conform to the following standard:

- Absolute 3-page total limit (excluding references), Arial 11 pt. font, ½ inch margins to outline the scientific justification and methodology to be used in the project.

- Cover Page - with Study Title and Name of Principal Investigator and Co-Investigators (not included in 3-page limit).

Recommended application components include:

1. Hypothesis and Specific Aims (1/2 page)
2. Background (1/2 page)
3. Approach (Study Design, Research Methods, and Statistical Analysis, include Study Duration) 1/2-1 page
4. Relevant Experience of PI and research team (1/2 page)
5. Anticipated Impact and Significance to SPLIT
6. Estimated Budget with Justification (1/2 page)
7. Literature cited (not included in 3-page limit)
8. Include a list of SPLIT data points being requested (provide CRF form and page number if possible) - not included in 3-page limit.
9. No Appendices are allowed.

Given the SPLIT charitable status designation and the relatively limited grant size (historically these have typically ranged from \$3,000 - \$10,000) no indirect costs will be paid, and should not be included in the budget estimate.

RFA's will be reviewed by an unbiased group of SIM's selected by the council. Any content (written or presented) resulting from an RFA will conform to all of the content review and submission guidelines identified in this document, and follow the SPLIT Acknowledgement standards. [See below- SPLIT-branded content review and submission process and Acknowledgements]

SPLIT Committees

General Principles

Leadership/Membership

Committee membership is open to all SIM's in good standing. There are no term limits for committee membership. Ongoing committee membership is determined by meeting the minimum participation requirements. [See [SPLIT Committee Membership Agreement Template- Administrative Folder](#)] Committee members not meeting the agreed upon membership expectations will be removed from the committee roster. Reinstatement to a Committee after failing to meet the minimum expectations will be at the discretion of the respective Committee Chair.

The Committee-specific members elect a Chair and Vice-Chair from the committee to 3-year terms respectively. [See Figure 2.] The Chair is responsible for participating on the SPLIT Council, setting the strategic vision and objective key results (OKR) for the committee as aligned with the overarching SPLIT objectives and determined by the

EC. The Chair is also responsible for presenting periodic updates to the Council as requested, and providing an update to the SPLIT membership during the Annual meeting. [See [SPLIT Committee Update Report Template](#) – Administrative Folder] The strategic visions and OKR updates will serve as semi-annual peer-reviewed committee progress reports.

Conference Calls/Meetings

Committees (ROC, Research, QICC, Education, Advocacy, and PFEP) meet by conference call on a monthly basis unless otherwise noted in the Committee-specific sections below. The TSM works with the Chair and Vice-Chair to determine agenda items prior to each call.

Proposal and Project Tracking

Each committee will use a Project Proposal Tracking method to identify and track the progress of all proposals and projects. This document will be updated and utilized as a mechanism for both Committee and Council members to understand the current proposals status.

Proposal Coordination with Other SPLIT Committees

A Committee may need to coordinate with other SPLIT committees regarding a proposal. For example, any proposal that requires direct access to SPLIT data or proposes to collect new data not presently captured, must be reviewed and approved by the ROC, the Multi-D Committee, and the DCC to determine priority and feasibility of accruing additional data points. SPLIT-funded proposal requests require EC review and approval in the absence of a Council-directed RFP. In all cases, the appropriate primary review Committee will first assess the merit of the proposal before determining whether a proposal should be forwarded to another committee for review.

Abstract, Manuscript, and Presentation Submissions

Any publications or presentations resulting from projects including SPLIT Registry data, membership or center-level survey data, or SPLIT/DCC study design or analysis must be peer-reviewed via the SPLIT content review and approval process. [See the Research Committee Section] The authors of any SPLIT-endorsed content must acknowledge SPLIT in any presentations or publications resulting from the use of SPLIT data/infrastructure. Manuscript authorship should include the "Society of Pediatric Liver Transplantation," and the manuscript methodology should reference the SPLIT

Registry data and specify the time period included. [See Acknowledgement Statement and Content Review Process in the Research Committee Section below] Violations of this guideline may result in a “Letter to the Editor” from the SPLIT Council regarding data use practices, and possible restrictions on future data use.

Registry Operations Committee (ROC)

Mission and Vision Statements

The ROC mission is to efficiently manage the SPLIT Data Registry and facilitate a complete and accurate data interface that serves as the platform for SPLIT’s evidence-based activities and legacy. This mission is accomplished by systematically managing the content of the CRF’s, establishing data definitions, developing and monitoring data quality objectives and processes, and generating reports for participating Registry sites. The ROC also oversees all Registry Site membership activities.

Leadership/Membership

In addition to the aforementioned leadership and membership standards (See Committee General Principles Section above), the ROC Chair, Vice-Chair, and members must be affiliated with a Registry Site. Physician ROC members must also be SIM’s in good standing. In addition, it is important to have adequate Coordinator representation on this committee to reflect their experience and impact on the ROC mission. Coordinators on the ROC must be affiliated with a Registry Site, but **do not** have to be SIM’s.

Conference Calls/Meetings

Call minutes are taken by the ROC Chairs and circulated by the DCC.

Transplant Center Registry Site Membership

The cornerstone of SPLIT’s mission and scope is dependent on the quality and quantity of entered Registry data that can be queried, analyzed, and disseminated to advance pediatric liver transplant healthcare.

The value in being a RSM includes access to:

- Activities directly contributing to progress in pediatric liver transplantation
- Registry and Center-level survey data
- Benchmarking tool query
- Annual Reports
- Data Analysis

- Opportunities to submit project proposals and participate in collaborative research or QI initiatives
- A network of experts for clinical care management questions and sharing best-practices
- US News & World Report recognition
- Potential for hosting an annual meeting
- Access to other SPLIT network resources

Transplant Centers that want to join the Registry must submit the [Registry application form](#)– [ROC Folder] available on the SPLIT website (splitdcc.org). The Registry application process is **not** designed to evaluate the merit of a center to join SPLIT, but rather to identify demographic information (i.e. names and contact information for program PI's, coordinators, administrators, or any other key personnel) to facilitate the RSM "onboarding process" through the DCC. The ROC will review these applications for completeness prior to submitting to the Council and the DCC.

Expectations for all SPLIT Transplant Center Registry Sites

Registry Site Annual Dues

The minimum expectations for all RSM's involve payment of annual dues, and input of patient data into the Registry. The Registry Site payments should be viewed as an investment in the future financial solvency of SPLIT and a collaborative commitment to shared Registry data integrity and implementation into research, quality improvement, and educational funding opportunities. It is the intent of SPLIT to eventually be a financially self-sustaining entity to optimize these objectives.

The ROC (with support from the DCC) will have responsibilities for billing RSM's. The ROC will be responsible for notifying the EC of RSM's with outstanding overdue annual dues.

Registry Site Data Entry Compliance Guidelines

SPLIT registry data entry compliance standards include: ≥75% patient enrollment, ≥80% value completion compliance, ≥80% form completion compliance. The ROC and the DCC will meet with RSM's whose data compliance is suboptimal, to identify strategies for support and improvement.

Expectations of an International Registry Member Site

Transplant centers outside of the United States and Canada may apply to join the Registry. All the same membership

requirements apply to these RSM's including annual membership payments and regulatory approvals. In contrast to a new U.S. RSM, new international Registry Sites are able to enter BOTH retrospective and prospective data. International RSM's will receive center-specific reports and have access to the online benchmarking tool, but international RSM data will not be incorporated into the Registry for cohort data analyses used to generate reports, research projects, manuscripts, or the denominator of BM tool data at this time.

Process for Data Requests (SPLIT Registry Member Site)

Any SPLIT RSM PI can request Registry data with or without DCC statistics analysis for:

1. Center-specific study (i.e. internal RSM use).
2. External use (i.e. data tables for book chapters or position statements, etc.).
3. Research/QI projects.

For #1 and #2 queries that are beyond the scope of the BM tool, data is requested by email to the DCC Rep (with cc: to SPLIT President and Treasurer) RSM PI's wishing to utilize SPLIT Registry data for any form of multicenter Research/QI research project, should follow the proposal submission process. For all data requests, Emmes will generate a work order [Emmes Sample Work Order Form-Administrative Folder] including itemization of estimated charges. Emmes will send the completed work order to the requesting PI, and cc: the EC. [See the Proposal Submission and Approval Process below] If SPLIT funds are being requested, EC approval must be obtained before moving forward with any data transfer, analysis, or invoicing.

Process for Data Requests (Individual SPLIT Member(s)- Including SPLIT Committees and Working Groups)

The data request process for SIM's is similar to the process for RSM's. In an attempt to leverage the innovative expertise of all SIM's while maintaining the benefits to the RSM's, SIM's generating Research or QI proposals that are **not affiliated** with a RSM must follow the proposal submission process. [See the Proposal Submission and Approval Process below] The added requirement is that a Co-Principal Investigator must be named from a RSM, and be included in the proposal.

Research Committee

Mission Statement

The Research Committee identifies, designs, and reviews research opportunities that leverage the SPLIT Registry and the collaborative SPLIT membership spirit to better the lives of children with liver transplant.

Research Project Priority

The committee is responsible for drafting and maintaining an **annual research priority**. SIM's and RSM's may propose research initiatives and projects, but the Research Committee will determine the annual research strategy based on available annual budget and the DCC resources. ***The purpose of the research priority is to manage projects, and justify the allocation of effort and resources to complete research deliverables for SPLIT.*** Additional proposals can and should be accepted and reviewed by the Research Committee outside of the proposed research priority, but these proposals may require an extramural (outside of SPLIT budget) funding mechanism and effort to support data acquisition and analysis, and may have lower priority for the DCC. This priority should be openly shared with prospective investigators and the DCC to transparently manage expectations and increase probability of efficient project completion.

Research Proposal Submission Process

Submitted proposal will be expeditiously triaged to the appropriate "approved," "conditional approval," or "not approved" decision. Any SIM who meets the Proposal Submission Criteria listed below can submit a research proposal and serve as the PI or Co-PI.

Research Proposal Submission Criteria:

1. No identified COI or unethical issues.
2. The PI must be a SIM in good standing.
3. If the proposal requires use of data from the SPLIT Registry or survey of Registry Site practices, the PI must be affiliated with a RSM in good standing. If the PI is **not** affiliated with a RSM, then the proposal must be submitted with a Co-PI from a RSM.
4. The proposal must identify the anticipated source of funding.
5. Proof of Human Subjects Protection training.
6. Secure data file storage and transfer application.

PI's submitting proposals must use the **SPLIT Project Proposal Application** [Research Committee Folder]. A budget plan must also be submitted, even if the proposed plan is for external agency funding. If the PI plans to fund the proposal with their institutional funds, this should also be noted in the budget plan. **All proposals should be submitted to the TSM for distribution to the appropriate Chair and Committee members.** The PI submitting the proposal will receive a confirmation of receipt by the TSM.

Proposals must be received at least 2 weeks prior to a scheduled call to be reviewed during that next committee call.

Research Proposal Review Process

The Research Committee is responsible for evaluating all research proposals generated for SPLIT. Upon receipt of a proposal, the Committee Chair will contact the committee members to identify **two** primary reviewers. For primary review, proposals must meet the Proposal Submission Criteria. Proposals that address topics that are not part of the current research priority as designated by the Research Committee will be reviewed and addressed **after** submitted proposals that align with the current research priority.

The purpose of the **primary review** is to determine:

1. The significance of achieving the specific aims.
2. The expertise of the investigators.
3. The innovation and overall methodology strategy.
4. The scientific impact of the completed project.

The primary reviewers document their proposal evaluation using the **SPLIT Proposal Review Form** [Research Committee Folder]. The completed review forms and the proposal will be distributed to all committee members for review at least **one week** prior to the next scheduled Committee conference call. All reviews should be conducted with the utmost confidentiality and should not be discussed outside of the committee. The primary reviewers lead the proposal discussion with the committee during the call. The proposal PI may be invited to provide a project overview and answer any committee questions during the open discussion call. Following acceptance of the primary review, the Research Committee Chair will forward the data collection portion of the proposal and a DCC "Work Order" to the ROC Chair and DCC Rep as a **secondary review** to assess the merit of:

1. The data methods plan. (Study design)

2. The cost estimate for data collection and cleaning.
3. Any requested statistical support.

This secondary review will be returned to the Research Chair and the PI **within 10 days** for final evaluation to determine any necessary revisions. The **final evaluation** of the proposal will be discussed during a closed session of the next Research Committee call that will not include the submitting PI. Either the Research Committee Chair or Vice-Chair will consolidate all pertinent committee discussion comments along with the written evaluation of the primary and secondary reviewers in one written summary (using the Proposal Evaluation Form). The final evaluation will be emailed to the PI immediately after the Committee call. PI's may contact the Committee Chair regarding any questions about the proposal evaluation. Once all recommended revisions have been addressed, the updated proposal should be re-submitted to the Chair for the committee's re-evaluation and approval. The Committee Chair will email the EC regarding the final evaluation of a proposal. During formal RFP periods, the submission and review process will be similar, but the review turn-around timelines may be different.

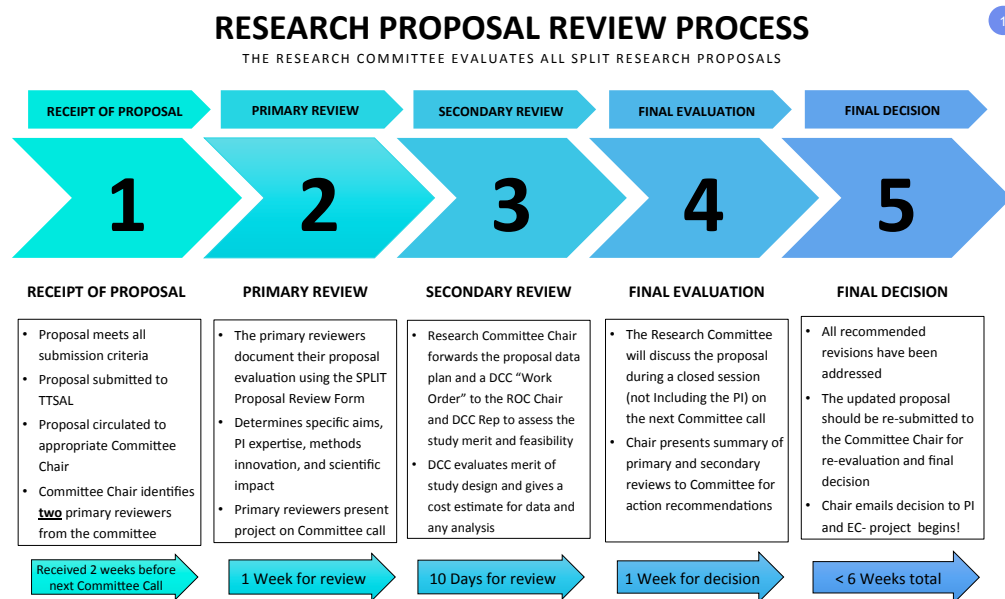


Figure 3. Research Proposal Review Process

SPLIT-branded Content Review Process for Publications, Presentations, or External Use

Any publication, presentation, abstract, position statement, educational material, grant application, social media post, or poster utilizing SPLIT-branded content or Registry/survey data must include allowance for the following:

1. An initial notification of the intent to submit SPLIT-branded content for external use is first made by the primary/corresponding author to the TSM. The TSM will then connect with the SPLIT Research Committee Chair and the SPLIT President.
2. The content will be circulated by the TSM and reviewed by a minimum of 2 individuals (a primary reviewer, a secondary reviewer) assigned by the SPLIT Research Committee Chair and the SPLIT President. ***The review process turnaround time is within 3 weeks of primary review.*** The content reviewer feedback to the submitting author will occur via the TSM, and receipt will be confirmed to facilitate any further discussion.
3. Acknowledgement of SPLIT in the authorship and title of any publication, presentation (poster/oral), or abstract. A sample acknowledgement statement is available in the Acknowledgement Statement section below.
4. Any other SPLIT-branded or endorsed materials should go to the TSM who will forward to the EC for expedient approval.
5. The Senior Author will send the final manuscript PDF to the TSM to add to the SPLIT Bibliography.

****Any disputes over SPLIT-branded content must be satisfactorily resolved prior to releasing the content to the public.***

Alternative Ad Hoc SPLIT-branded Content Review

Dissemination of high-integrity and quality content in an ethical and timely fashion is a priority of SPLIT. As such, the Research Committee content review process is the primary mechanism by which SPLIT-generated content is reviewed and approved for external use. In the event that circumstances prevent timely and non-conflicted execution of the usual process for all the various forms of SPLIT-branded content that may require approval, ad hoc content reviewers can review abstracts, manuscripts, grant applications, posters, flyers, social media posts, or formal presentations. This ad hoc group reports to the Council, and can be specifically convened from members of Council, Research, Education, or QICC Committees to evaluate the content, scientific methods, conclusions,

recommendations, and any COI's that are proposed from any SPLIT project.

At-large surgical and medical members of the council will share in the responsibility of ad-hoc content review with the Research Committee.

SPLIT Acknowledgements

SPLIT Registry data in all of its various forms and iterations is the sole property of SPLIT Inc. As such, for publications, book chapters, figures, and abstracts utilizing any SPLIT Registry Data, survey results from the SPLIT membership, or conceptual study design provided by a SPLIT committee or working group, SPLIT should be acknowledged as an author. [Obtain the updated Registry Site and PI Reference List maintained by the ROC Chair]

Sample Acknowledgement Statement

The bolded statement below has been designed as template "cut and paste" language to be used in the acknowledgements section for any SPLIT-branded publicized content. It is imperative that any such content be vetted through the review processes described in this manual to receive SPLIT endorsement.

The authors would like to acknowledge the Society of Pediatric Liver Transplantation, the data contributions, proposal review, study design revision, and project oversight approval by SPLIT, Inc., the SPLIT Registry, and Emmes. Funding for data preparation and management was provided by _____. The data analysis, conclusions, and any recommendations in this body of work are supported by SPLIT.

Quality Improvement Clinical Care Committee (QICC)

Mission and Vision Statements

The QICC mission is to strategically identify critical variations in transplant outcomes and target the actionable practices that impact quantity and quality of life after pediatric liver transplant. Unlike traditional research projects, this mission is accomplished by benchmarking and disseminating best practices, implementing the latest healthcare technologies, facilitating a platform for shared clinical projects, identifying potential funding opportunities, and promoting a culture of continuous quality improvement.

QI Proposals

The committee evaluates all QI proposals and supporting documents (i.e. surveys, bench-marking figures, or PDSA diagrams) generated within SPLIT. QICC sets the project priorities to facilitate DCC resource allocation, budgeting, and strategic plan development.

QI Proposal Submission Process

QI project proposal submission is the same as the research proposal submission process. [See Research Proposal Submission Process] All PI's submitting proposals to the QICC committee must use the [SPLIT Project Proposal Application](#)- [QICC Folder]. This document includes a budget plan with potential funding source options. All proposals should be submitted to the TSM 2 weeks prior to the next Committee call where the proposal will be discussed. The PI submitting the proposal will receive a confirmation of receipt by the TSM. Proposal applicants utilizing surveys are encouraged to use the ["Effective Collaborative Survey"](#)- [QICC Folder] guidance document.

QI Proposal Review Process

The QI proposal review process is similar to the Research proposal process above. [See the Research Proposal Review Process] The **primary reviewers** are responsible for documenting their evaluation of the proposal using the [QICC Concept Proposal Review Form](#)- [QICC Folder]. It is expected that all accepted proposals will be periodically reviewed on monthly committee calls, and that final projects will be briefly presented at the Annual Meeting to the general membership.

Multi-Disciplinary Professionals Committee (Multi-D)

Mission and Vision Statements

The mission of the Multi-Disciplinary (Multi-D) Committee (formerly the Coordinators/ AHP committee) is to improve the overall timely entry of quality data into the SPLIT Registry, and promote coordinator and other (non-physician) AHP engagement within SPLIT. This mission is accomplished by identifying and overseeing educational opportunities, project study implementation, data collection, quality initiatives, and research opportunities.

Conference Calls/Meetings

Members meet by conference call **every two months (6 calls/year)**. The TSM determines the agenda with the Chair

and Vice-Chair prior to each call. The DCC representative participates on these calls as a liaison to the ROC, and to answer any DCC-related issues.

Education Committee

Mission and Vision Statements

The mission of the Education committee is to educate and mentor health professionals in pediatric liver transplantation. This mission is achieved by sponsoring and facilitating trainee education, interfacing with other societies, and planning the Annual meeting.

Leadership/Membership

In addition to the aforementioned leadership and membership standards (See Committee General Principles Section above), the members elect a Physician Co-Chair, Coordinator/Allied Health Professional Co-Chair and Physician/Coordinator Vice-Chairs from the committee to serve 3-year terms respectively.

SPLIT Annual Meeting

Selection of Annual Meeting Sites

The Annual SPLIT meeting is the showcase for the SPLIT mission. On an annual basis, the Education committee will announce and distribute a Request for Applications (RFA) to RSM's interested in hosting the next SPLIT Annual Meeting. This RFA is announced in the Fall, two years in advance of the applicable meeting, and will include any key features being sought for the finalist. All SPLIT RSM's (in good standing) are eligible to apply. Applications are **primarily evaluated** and scored [See Annual Meeting [Proposal Site Scoring Rubric](#)- Education Folder] by members of the Education Committee on the basis of:

1. General scientific emphasis, concepts, and themes.
2. Proposed agenda.
3. Expertise and diversity of proposed speakers.
4. Structure and cost for administrative support.
5. Detail and feasibility of meeting budget.
6. Potential meeting highlights and unique audience offerings.

The Education Committee Chair has the discretion to provide guiding information to applicants to improve the application quality. Composite scores will be blinded from reviewers and totaled by the Committee Chair. The totaled scores will then be forwarded to the **secondary evaluators** consisting of previous annual meeting host alumni (MHA) dating back to 2013. Applicant Finalists will briefly

present their intended program by conference call to the MHA group, and answer clarifying questions. Application scores are not the sole criterion for determining the awardee. Any concern for a COI should be reported to the Education Committee Chair and to the EC. Persons with a COI should recuse themselves from all discussion and evaluation. In the case of a COI the EC may select other SIM's to evaluate applications. The Education Committee Chair will submit the recommendation of the MHA's to the EC for final approval. The Education Committee Chair will notify the applicants of the selected Site with appropriate feedback for the Sites not selected. The TSM will archive all applications.

Annual Meeting Planning

The committee has developed project planning and Annual meeting checklist documents- [Education Committee Folder] to serve as a guide to Sites hosting the annual meeting. The timeline highlights the specific planning milestones. In addition to hosting the meeting, the host center determines the meeting dates, venue, the agenda, identifying speakers, managing the meeting budget, developing the meeting website content, securing qualified CME/CEUs, developing the scientific program, and performing an evaluation of the meeting. Information regarding annual meeting programming, registration, and accommodations will be found at www.splitannualmeeting.com.

Travel Grant Awards

Every year SPLIT provides travel grants to fellows, junior faculty, and coordinators to support meeting travel-related costs. The Committee determines the annual number of awards based on available budget. Applicants are required to complete the Physician or Multi-D Travel Grant application- [Education Folder] The applicant requirements, criteria for award consideration, and the scoring process are included on the application.

Advocacy Committee

Mission and Vision Statements

The Advocacy Committee members are activists for children awaiting and following liver transplant, with the objective of eliminating preventable waitlist and post-transplant morbidity and mortality. This is accomplished through a data-driven approach to actionable patient issues

surrounding equitable transplant care access, evaluation, pre-transplant management, and organ allocation policy.

Leadership/Membership

In addition to the aforementioned leadership and membership standards (See Committee General Principles Section above), the Advocacy Committee Chair serves as a liaison to the PFEP committee and facilitates communication and dialogue with the SPLIT Council. Ongoing committee membership is contingent on meeting the minimum Committee participation requirements. [See [Advocacy Committee Member Agreement](#)-Advocacy Committee Folder]

OPTN/UNOS Liaison role

The Advocacy Committee will provide an Annual meeting update to the SPLIT membership on OPTN/UNOS, pediatric liver allocation, and relevant new policies impacting pediatric liver transplant healthcare.

The Advocacy Committee will be responsible for generating twice-yearly responses to OPTN/UNOS Public comment, obtaining approval from members of the committee, EC or Council, and soliciting input from the wider membership. Response drafts will begin prior to the submission deadline, with a 1-week turnaround for SIM feedback, and then an additional 1-week for Advocacy Committee feedback, and submission to the EC for final approval.

Patient and Family Engaged Partners (PFEP)

Mission and Vision Statements

The PFEP mission is to bridge the gap between patients, families, the transplant team, and other healthcare professionals to improve outcomes of pediatric liver transplantation. The PFEP mission is accomplished by utilizing social media and online websites to disseminate educational tools/resources, and facilitate mentorship programs and committee member networking opportunities. [See [PFEP Flyer](#)- PFEP Committee Folder]

Leadership/Membership

Committee membership is open to all children and parents of children who received a liver transplant, and there are no term limits. The members elect a Chair and Vice-Chair from the committee. Each officer will serve a three-year term. The Vice-Chair will assume the role as committee Chair at the end of three years. As stated in the Advocacy Committee section, the Advocacy Committee Chair will serve as the PFEP Committee liaison.

PFEP-SPLIT Content Approval Process

PFEP is a unique committee that partners with SPLIT to personify and amplify the patient/family voice in promoting the SPLIT-PFEP mutual mission. Any content (written, verbal, or virtual) that PFEP produces on behalf of SPLIT or referencing SPLIT should be shared with the Advocacy Committee, and then approved by the Council or EC. Any proposals for Research or QI projects should follow the proposal approval process. [[PFEP Project Policy](#)- PFEP Committee Folder] PFEP committee members submitting research or QI project proposals should partner with a RSM as a Co-PI and follow the proposal submission process. [See SPLIT Content Submission and Review Process]

OPTN/UNOS Proposal Public Comment role

The PFEP Committee will work closely with the Advocacy Committee in providing patient and family-centric perspective on appropriate OPTN/UNOS proposals. PFEP will provide updates to the Council and the SPLIT membership as appropriate to generate support for proposals and education on the patient-voice position.

PFEP Project Proposal Submission

All sub-committee leads submitting project proposals should use the [PFEP Project Proposal Template Form- \[PFEP Committee Folder\]](#). This document will include the name of the subcommittee, it's leaders and members, name of the project, background, objectives, scope, estimated timeframe, budget (if applicable) and how the progress will be monitored. **All proposals should be submitted to the TSM.** The subcommittee submitting the project proposal will receive confirmation of receipt by the Chair or Co-Chair.

PFEP Proposal Review Process

Once a project proposal has been received, the Chair or Co-Chair will then contact the EC leadership who will disperse to its members for discussion and review and in the end for final approval. If any additional information is needed, the EC can reach out to the PFEP Chair or Co-Chair with questions.

Working Projects

Once approved, the subcommittee can then begin work. Updates on the project can be shared on monthly calls as an agenda item. Any work that is requiring collaboration and representing SPLIT will require review and approval by the EC prior to moving forward. As a patient advocacy group,

all work will be represented with full SPLIT Council support.

Operations Manual Use and Revision

This operations manual represents the collective thoughts, practices, dedication, future direction, and spirit of the SPLIT community, its partners, and stakeholders. The description of processes, relationships, roles, objectives, and practices are best intended as the reasonable representation of the SPLIT collaborative and mission. It is further intended that the best interests of the pediatric liver transplant patients and their families will remain the singular focus of this organization. To ensure a culture of innovation and accuracy, the Council will review and approve this manual at each Annual SPLIT meeting. This manual will **always** reflect the collegial nature and joy that each SPLIT member brings to further the SPLIT mission.

Council

SPLIT Council Role	Council Member
President	Evelyn Hsu
President-Elect	Manuel Rodriguez-Davalos
Past President	Beau Kelly
Treasurer	Vicky Ng
Secretary	Vicky Ng
ROC Physician Chair	James Squires
ROC Multi-D Co-Chairs	Susan Feist, Julie Economides
Research Committee Chair	Katryn Furuya
QICC Committee Chair	Bernadette Vitola
Education Committee Co-Chairs	Alisha Mavis (Physician), Jody Weckwerth (Multi-D)
Multi-D Committee Co-Chairs	Mary Riordan, Dana Mannino, Jessica Hollenbeck (RDS)
Advocacy Committee Chair	Emily Perito
PFEP Committee Co-Chairs	Jennifer White, Brittany Munn
Medical Physician-at-large (MAL)	Saeed Mohammad
Surgeon-at-large (SAL)	Adam Griesemer
DCC Representative	Jeff Mitchell
TSM Representative	Katie Tait

Website URL's:

www.TTS.org - TTS

www.Splitdcc.org - Registry Operations

www.splitannualmeeting.com - SPLIT Annual Meeting