ISHLT International Thoracic Organ Transplant (TTX) Registry

Data Governance Policy

Version 1.2 | Registry Medical Director | August 2026

Reviewed and Approved by the ISHLT Research Oversight Committee — August 2026

1. Purpose and Guiding Principles

The ISHLT TTX Registry collects longitudinal thoracic transplant data from collectives and centers worldwide. Registry data underpin clinical guidelines, inform global practice, and create substantive research and educational value for early-career investigators and the broader ISHLT membership.

This document establishes the policy governing how the ISHLT TTX Registry data are requested, reviewed, released, and used by the community. The policy is designed to:

- Maximize open, timely access for qualified ISHLT investigators
- Protect the Registry's Steering Committee annual analyses from pre-emption
- Maintain consistent data quality by releasing two separate cleaned datasets for heart and lung per annual cycle
- Ensure appropriate use through a streamlined but accountable review process
- Provide transparency about the Registry's current data scope and available outcomes

This policy applies to all external requests for TTX Registry data. Internal analyses conducted by the Steering Committee and its working groups are governed separately under the annual analysis plan (Section 4).

2. Governance Structure

2.1 Registry Medical Director

The Registry Medical Director holds overall responsibility for this policy, annual dataset preparation, and compliance oversight. The Medical Director chairs the Steering Committee review process and serves as the point of escalation for contested decisions.

2.2 Associate Directors

The TTX Registry has four Associate Directors, each responsible for a distinct population:

- Adult Heart Transplantation
- Pediatric Heart Transplantation
- Adult Lung Transplantation
- Pediatric Lung Transplantation

Each Associate Director serves as the first-line reviewer for incoming proposals relevant to their population. Pre-review by the responsible Associate Director is required before a proposal advances to the full Steering Committee.

2.3 Steering Committee

The Steering Committee includes the DCC's lead biostatistician, the ISHLT Registry Medical Director, Vice Chair, and the four Associate Directors (Adult Heart, Adult Lung, Pediatric Heart, Pediatric Lung). Associate Director terms are three years, with one additional overlap year to mentor the incoming Associate Director.

The full Steering Committee reviews proposals monthly during regularly scheduled calls. The committee approves, requests revision of, or declines proposals by consensus. Decisions are communicated to requestors within 7 days of the relevant call.

2.4 Data Coordinating Center (DCC)

The DCC prepares the annual cleaned datasets (one heart, one lung) and executes approved data releases. Upon proposal submission, the DCC performs an initial feasibility check to confirm that the requested variables and outcomes exist in the current datasets before the proposal is routed to the relevant Associate Director. The DCC does not perform analyses for external requestors under this model; data are released directly to approved investigators.

2.5 ISHLT Research Oversight Committee (ROC)

This policy, and any material amendments, requires approval by the ISHLT Research Oversight Committee prior to implementation. The ROC is not involved in individual proposal review.

3. Dataset Description and Scope

3.1 Annual Release Cycle

To maintain data integrity and minimize DCC burden, the TTX Registry prepares two cleaned, de-identified SAS datasets per calendar year (one heart, one lung). The annual datasets will aim to be available for data requests in April–May of each calendar year. Datasets are prepared by the DCC.

3.2 Current Available Data — Transparency Statement

Investigators are strongly encouraged to review the list of variables included in the datasets and the corresponding level of completeness documents available on the ISHLT Registry website before submitting a proposal. Proposals requesting outcomes not currently available will not be feasible and will be declined at pre-review.

4. Protected Annual Steering Committee Analyses

Each year, the Steering Committee defines a set of analyses to be conducted as part of the Registry's annual report cycle. To prevent pre-emption of these analyses by external requestors:

- The TTX Registry will publish a list of protected analysis topics concurrent with the data release.
- Proposals that substantially overlap with a protected analysis will be declined for the current cycle and may be resubmitted once the protected analysis has been accepted for publication.

- The Steering Committee defines overlap; the Medical Director makes the final determination when ambiguous.

5. Requestor Eligibility

Data requests may be submitted by individuals who meet all of the following criteria:

- Active ISHLT member in good standing at the time of submission
- Affiliated with an academic, clinical, or research institution (industry-sponsored requests are not eligible)
- IRB/ethics committee review is not required by ISHLT for use of de-identified Registry data; however, investigators should confirm with their own institution whether local IRB review or exemption is required per institutional policy, and comply accordingly

There is no requirement that requestors be affiliated with a TTX Registry-contributing center. Early-career investigators (trainees, fellows, or junior faculty within 6 years of training completion) are specifically encouraged to apply; proposals from early-career investigators will note this status, which the committee views favorably.

There is no formal limit on the number of concurrent approved projects per investigator. The Steering Committee may consider a requestor's history of completing prior approved projects as one factor in review, particularly when a requestor holds multiple active datasets with no resulting output. This is a discretionary consideration, not a threshold requirement, and will be applied transparently with the opportunity for the requestor to respond.

6. Proposal Submission and Review Process

6.1 Submission

Proposals are submitted on a rolling basis throughout the year using the TTX Registry Data Request Form, available for download on the ISHLT Registry website. Completed forms should be emailed to ishlthelp@unos.org. There is no fixed submission deadline; proposals are reviewed at the next monthly Steering Committee call following pre-review completion.

To meet the ISHLT Annual Meeting abstract deadline (typically October), proposals should be submitted no later than August 1 to allow time for review, data release, and preliminary analysis.

6.2 Required Proposal Elements

Proposals should be concise. The TTX Registry Data Request Form, available for download on the ISHLT Registry website, captures all required elements. A clear hypothesis and analytic approach are sufficient; an extensive literature review or detailed statistical plan is not required at submission.

6.3 Associate Director Pre-Review

Upon submission, each proposal first undergoes a DCC feasibility check (within 5 business days) to confirm that the requested variables and outcomes are available in the current dataset. Proposals that are not feasible at this stage are returned to the requestor with explanation. Proposals that pass DCC feasibility review are routed to the Associate Director responsible for the relevant population, who assesses:

- Feasibility given available registry variables (Section 3.2)

- Overlap with protected Steering Committee analyses (Section 4)
- Overlap with other currently approved external projects
- Scientific merit and clarity of the research question

The Associate Director may contact the requestor for clarification before the Steering Committee call. Where a submitted proposal is adjacent to — but not duplicative of — an already-approved project, the Associate Director may facilitate an introduction between investigators to explore potential collaboration. This is offered as a resource, not a requirement; investigators retain full autonomy over their research teams and authorship decisions.

6.4 Steering Committee Review

Proposals that pass pre-review are reviewed at the next monthly Steering Committee call. The committee makes one of three determinations:

- Approved — data release proceeds
- Revision requested — requestor is given specific feedback and may resubmit
- Declined — with written rationale provided

Review is not blinded. There is no competitive scoring; this is not a grant mechanism. The goal is to ensure the proposed work is feasible, non-duplicative, and scientifically sound.

6.5 Decision Notification and Data Release

Decision letters are sent within 7 days of the Steering Committee call. For approved proposals, data are released following execution of the Data Use Agreement, available for download on the ISHLT Registry website. Release is via secure file transfer; the standard release format is a single cleaned, de-identified dataset file (SAS).

Approximately 12 months after the date of data release, the TTX Registry may send the approved investigator a brief status inquiry. The purpose of this check-in is supportive: to confirm the project remains active, update the public project log (Section 6.6), and identify any ways the Registry or the relevant Associate Director can assist with completion. The status inquiry will ask: (1) Is the project still active? (2) What is the current status? (3) Is there anything the Registry can do to support completion? A brief email reply within 30 days is all that is required.

6.6 Public Project Log

The ISHLT TTX Registry maintains a publicly accessible log of all currently approved data requests on the ISHLT website. The log includes project title, PI name and institution, organ population(s), broad analytic topic, and current status. Projects are added upon approval and removed upon confirmation of manuscript publication.

7. Data Use Agreement

All approved requestors must execute the ISHLT TTX Registry Data Use Agreement (DUA) prior to data release. The DUA is available for download on the ISHLT Registry website. Key provisions include:

- Data may be used only for the research purpose described in the approved proposal
- Data may not be transferred to persons not listed on the approved proposal without written registry approval
- Data may not be used to identify any individual patient or institution
- Data may not be sold

- The PI is responsible for ensuring all collaborators comply with DUA terms
- The PI confirms compliance with their institution's IRB requirements
- The PI agrees to respond to TTX Registry progress queries
- Data are destroyed upon completion of the project

8. Publication and Presentation Requirements

8.1 Pre-Submission Review

All abstracts, presentations, and manuscripts using TTX Registry data must be submitted to the ISHLT TTX Registry for review at least 14 days prior to submission or presentation time. Submission for review does not constitute approval to publish; it constitutes an opportunity for the Registry to identify errors, confidentiality concerns, or conflicts with Registry policy. The designated Associate Director will coordinate review and provide written clearance or feedback within the 14-day window.

8.2 Journal and Conference Policy

Manuscripts arising from the ISHLT TTX Registry data must be submitted to the Journal of Heart and Lung Transplantation or JHLT Open as the journals of first refusal. If the manuscript is determined to be outside the scope of these journals or is not accepted, submission to an alternative peer-reviewed journal is permitted. Abstracts arising from Registry data must be submitted first to the ISHLT Annual Meeting prior to submission to any other scientific meeting.

8.3 Required Acknowledgment and Disclaimer

All publications and graphic presentations must include the following standard language:

> *"The data have been provided by the ISHLT International Thoracic Organ Transplant (TTX) Registry. The interpretation and reporting of these data are the responsibility of the author(s) and do not necessarily reflect the views of ISHLT."*

Publications must also note the effective date of the dataset used (e.g., "Based on ISHLT TTX Registry data as of [month, year]").

8.4 Authorship

Authorship is determined by the PI in accordance with ICMJE criteria. The TTX Registry does not mandate inclusion of Steering Committee or Associate Director members as co-authors, though the responsible Associate Director's contributions during review and project support may merit authorship and should be considered in that context. If contributions do not merit authorship, acknowledgement can be considered.

9. Data Retention and Destruction

Investigators will destroy the dataset upon completion of the proposed project, in accordance with their institutional data retention policies.

10. Non-Compliance and Enforcement

Failure to comply with the terms of the DUA or this policy may result in one or more of the following:

- Revocation of data access
- Restriction of future data requests from the PI and/or their institution
- Notification to the ISHLT Research Oversight Committee (ROC)

The Registry Medical Director, in consultation with the Steering Committee, determines appropriate remediation. Appeals may be directed to the ISHLT Research Oversight Committee.

11. Process Timeline Summary

The table below summarizes key process milestones under this governance model.

Timepoint	Action	Responsibility
April–May	Steering Committee finalizes annual analysis plan; protected analyses identified for current cycle	Registry Medical Director + Associate Directors
Rolling (year-round)	Proposals submitted via ISHLT website	ISHLT Members
Within 5 business days of submission	DCC feasibility check; proposal routed to Associate Director if feasible	DCC
Before monthly Steering Committee call	Pre-review by relevant Associate Director	Associate Director
Monthly Steering Committee call	Proposals reviewed; decision (approve / revise / decline) communicated	Steering Committee
Within 7 days of SC decision	Decision notification sent to requestor; DUA executed; dataset released	DCC + ISHLT Registry admin support team
At least 14 days prior to abstract submission	Draft abstract submitted for Registry review	PI / Requestor
At least 14 days prior to presentation	Draft presentation submitted for Registry review	PI / Requestor
At least 14 days prior to manuscript submission	Draft manuscript submitted for Registry review	PI / Requestor
Suggested: within 2 years of data release	Manuscript submitted for publication	PI / Requestor
~12 months from data release	Registry sends brief status inquiry to PI; response expected within 30 days	DCC + ISHLT Registry admin support team

12. Policy Review and Amendment

This policy will be reviewed by the Steering Committee no less than annually. Substantive amendments require approval by the ISHLT ROC. Administrative or clarifying amendments may be

made by the Registry Medical Director with notification to the Steering Committee. The version date and revision history will be maintained at the top of this document.

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