Sample and Data Sharing Policy

Version 4.0
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What is covered in this document

This document describes the policies and procedures governing the sharing of NIAID/ITN clinical and mechanistic datasets, biological specimens, and associated research materials generated through ITN-supported studies. It outlines the requirements for public data release, investigator requests for access to NIAID/ITN resources, review and approval processes, and the transfer of approved samples, data, and research materials for scientific research purposes.

What is ***not*** covered in this document

Publications Policy & Procedures

ITN TrialShare Terms of Use

ITN TrialShare Data Access and Usage Policy

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Abbreviations

DTA	Data Transfer Agreement
IRB	Institutional Review Board
ITN	Immune Tolerance Network
LPLV	Last Patient Last Visit
MTA	Material Transfer Agreement
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health

1.0 Goals and Scope of this Policy

1.1 Policy Goals

The Immune Tolerance Network (ITN) is committed to maximizing the scientific value of research resources generated through its studies by facilitating responsible and equitable sharing of samples, data, and associated research materials. Consistent with the National Institutes of Health (NIH) Data Management and Sharing Policy, the ITN supports the broad and timely dissemination of scientific data while ensuring that participant privacy, informed consent provisions, ethical obligations, regulatory requirements, and contractual commitments are appropriately protected.

The goals of this policy are to promote transparency, reproducibility, and scientific advancement; encourage the responsible use of valuable research resources; ensure compliance with applicable NIH policies and federal regulations; and establish a fair and consistent framework for evaluating and fulfilling requests for NIAID/ITN samples and data.

All sharing of NIAID/ITN samples, data, and associated research materials will be conducted in accordance with applicable federal laws and regulations, NIH policies, informed consent requirements, and other applicable regulatory and ethical requirements. This includes, but is not limited to, the NIH Policy on Enhancing Security Measures for Human Biospecimens (“NIH Biospecimen Security Policy”). ITN sample and data sharing activities will be evaluated against the applicable requirements in effect at the time of the proposed release or transfer.

1.2 Scope

This policy applies to the sharing of NIAID/ITN clinical, specimen, and mechanistic study data, as well as biological specimens and associated research materials generated through ITN-supported studies. The policy outlines the processes and requirements governing both public data release and investigator requests for access to NIAID/ITN data and specimens. This policy governs the secondary sharing of samples, data, and associated research materials for research purposes and does not govern protocol-required collection, processing, shipment, testing, storage, or reporting activities conducted as part of an ongoing study.

Data release is accomplished by making appropriate datasets publicly available through the ITN TrialShare web portal. The guidelines for timing of public data release described in this document will be followed by the ITN as closely as possible, taking into consideration available resources and the volume and complexity of data to be released. In all cases, data may be released earlier than the timelines described herein if agreed upon by the study investigators and ITN Leadership.

Requests for access to NIAID/ITN specimens, non-public datasets, or other research materials are subject to review and approval in accordance with this policy and any applicable informed consent restrictions, regulatory requirements, contractual obligations, and NIH policies.

Requests from investigators located outside the United States require additional review and approval by NIAID prior to the release of samples, data, or other research materials. While investigators outside the United States are eligible to submit requests for access to NIAID/ITN samples and data, ITN funding is not available to support collaborative research projects conducted at non-U.S. institutions.

2.0 Sample and Data Sharing Policy

The goal of the ITN Sample and Data Sharing Policy is to maximize the scientific value of samples and data generated through NIAID/ITN-supported studies by enabling ITN study teams and independent investigators to make appropriate use of mechanistic study samples and associated data. Such use may include research aimed at advancing the understanding of immune tolerance mechanisms, validating findings, and supporting ancillary scientific investigations.

The ITN maintains stewardship and oversight of mechanistic samples collected through NIAID/ITN-supported studies and stored within the ITN repository, as well as associated non-public datasets. Requests for access to samples and data are subject to review and approval by ITN Leadership and must comply with applicable informed consent restrictions, regulatory requirements, NIH policies, and other obligations governing the materials.

Clinical trial data are generally made publicly available through the ITN TrialShare portal 18 months after the last participant last visit (LPLV) or upon publication of the primary study manuscript, whichever occurs first.

3.0 Procedure

Once ITN clinical trial data have been publicly released through TrialShare, requests for access to NIAID/ITN samples and/or data may be submitted under the following categories:

1. **ITN Scientific Objectives** – Sample/Data Requests that are relevant to immune tolerance and support the scientific objectives of the ITN study, including, but not limited to, analyses described in the mechanistic components of the study protocol. These requests utilize existing ITN resources and do not require additional funding, assays, or analytical support. Publications resulting from these projects will follow the ITN Publication Policy.

2. **Collaborative Ancillary Studies** – Sample/Data Requests submitted as a collaboration between an ITN Biologist and an external investigator for research that is ancillary to, but aligned with, the immune tolerance objectives of the study as defined in the protocol. External resources, including assays, analytical support, or funding, are available to support the proposed work. Publications resulting from these projects will follow the ITN Publication Policy. ITN funding is not available to support collaborative research projects conducted at non-U.S. institutions.

3. **Independent Ancillary Studies** – Sample/Data Requests submitted by investigators from the broader scientific community for research that is ancillary to the immune tolerance objectives of the study and is not conducted as an ITN collaboration. The proposed project must be supported by resources independent of the ITN.

All requests must be submitted using the TrialShare Sample/Data Request Form and must include a clear description of the proposed study design, scientific rationale, and planned analyses. Requests should specify the types and quantities of samples required (e.g., cell numbers, serum or plasma volumes) to allow evaluation of the request in the context of available inventory and other planned or proposed studies. Where multiple sample and/or assay requests are proposed,

priorities should be clearly identified. Requests submitted in other formats will not be considered.

Upon receipt, Sample/Data Requests will be reviewed by ITN Leadership. Any request from an investigator located outside the United States that involves the transfer of NIAID/ITN samples, data, or other research materials must be submitted to NIAID for review and approval prior to release, regardless of whether ITN funding is requested.

The ITN will notify the requesting investigator of the status of their request within four (4) weeks of submission whenever possible. Requests requiring NIAID review may require additional time.

Approval of any Sample/Data Request is contingent upon confirmation that the proposed research has been reviewed and approved by, or determined exempt by, the requesting investigator's Institutional Review Board (IRB) or equivalent ethics review body, as applicable.

Prior to release or transfer, ITN will confirm that the proposed sharing is permissible under applicable federal laws and regulations, NIH policies, informed consent requirements, and any other applicable restrictions. Human biospecimens will not be distributed to institutions or parties when such distribution is prohibited by the NIH Biospecimen Security Policy or other applicable federal requirements.

Additionally, if approved, the transfer of NIAID/ITN samples, data, or other research materials to the requesting investigator will not occur until all agreements required for the approved transfer, including applicable Material Transfer Agreements (MTAs), Data Transfer Agreements (DTAs), and sponsor-required documentation, have been fully executed.

Following approval of a Sample/Data Request, an ITN Biologist or Core Operations Manager will work directly with the requesting investigator to coordinate sample selection, verify that all required approvals and agreements are in place, and facilitate the transfer of NIAID/ITN samples, data, or other research materials.

4.0 Contact Information

Sample requests should be sent to:

Philip Bernstein, Ph.D. Submissions@immunetolerance.org
Executive Director, Strategic Review and Planning
Immune Tolerance Network
1201 Ninth Ave
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5.0 Revision History

Date	Version	Changes	Author
8/27/2019	3.0	Update URL links and Bethesda address	Olivia Doyle
6/23/2026	4.0	Updated URL links, address, policy updates	Mary Roy