



Sample Sharing Policy

What is covered in this document

This document describes the policy and procedures for making optimal use of mechanistic samples collected from ITN clinical trials and stored within the ITN repository.

What is not covered in this document

Publications Policy & Procedures available at:

<http://www.immunetolerance.org/PublicationsPolicy>

ITN TrialShare Terms of Use available at:

<https://www.itntrialshare.org/tsstatic/Terms%20Of%20Use.html>

ITN TrialShare Data Access and Usage Policy available at:

https://www.immunetolerance.org/ITN_TrialShare_Access_Use_Policy.pdf

ITN Data Sharing Policy available at:

https://www.immunetolerance.org/ITN_Data_Sharing_Policy.pdf

ITN internal Standard Operating Procedures which cover technical procedures necessary to make study data public on ITN TrialShare

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Abbreviations

ITN – Immune Tolerance Network

NEC – Network Executive Committee

1.0 Sample Sharing Policy

The goal of the Sample Sharing Policy is to allow ITN study teams and independent investigators to make optimal use of all mechanistic study samples stored within the ITN sample repository for determining tolerance mechanisms and supporting (ancillary) scientific studies.

The ITN maintains responsibility for the use of mechanistic samples collected from ITN clinical trials and stored within the ITN repository. The design of mechanistic studies and selection of samples to be used are decided cooperatively by the trial Protocol Chair (trial PI) and the ITN leadership (Department, Network and Deputy Directors). The ITN and the trial PI will have exclusive use of all samples for 18 months after the last patient has completed the study. Prior to this, sample requests from non-ITN community members must be approved by the PI along with the ITN. After the 18-month period, the ITN will evaluate all requests for use of samples for studies not previously planned within the protocol by the procedure outlined below.

Proposed mechanistic studies described in an ITN trial protocol will be evaluated at the appropriate time during the trial (e.g. upon reaching a clinical endpoint); all assays may not necessarily be performed for all participants at each time point. Decisions to perform these (or alternative tolerance) assays will be jointly made with the PI and the ITN leadership and depend upon the clinical outcome, mechanistic rationale, sample availability, statistical and scientific planning, and current technologies to be utilized. For example, in the absence of an anticipated clinical effect, the assays performed by the ITN may be minimal. For studies where an anticipated clinical endpoint was not met, the PI will be informed that those mechanistic samples may be used for other assays in other studies, including those by other investigators contingent upon approval by the ITN.

2.0 Procedures

Proposals in the following categories from PIs or other members of the community will be considered:

1. Proposals relevant to immune tolerance in which samples and ITN resources are being requested (including, but not limited to those, that have been written into the mechanistic portions of the ITN protocol) and will be analyzed without need for additional resources (e.g., funding or analysis).
2. Collaborative proposals that are ancillary to the tolerance objectives of the study as defined in the ITN protocol in which samples are being requested but external resources (e.g., assays, analysis, or funding) are available.
3. Proposals ancillary to tolerance in which samples are being requested from the community at large; these proposals require external funding.

Proposals in category 1 and 2 will be reviewed by the ITN Network Directors (and the protocol chair for samples from studies prior to 18 months after the last patient visit). Proposals from category 2 (originating outside of the ITN Study Team or Assessment Groups) and for all proposals in category 3 will require NEC approval and may require review under the ITN's standard concept proposal review process

(https://www.immunetolerance.org/ITN_Concept_Proposal_Guidelines.pdf).

Proposals should be brief (2-3 pages) and describe the study design and rationale (standard forms are available upon request). They should be specific regarding sample types and amounts of stored samples required (i.e. specific cell number requirements, or serum/plasma volumes) so that the request can be evaluated in the context of all planned and proposed trial studies. Priorities for multiple sample and/or assay requests should be indicated. All proposals require budgets that include both estimates of internal (ITN) and external resources (assistance from the ITN Central Office is available for estimating budgets).

All sample requests not included in the original mechanist study plan, whether presented through the Study Management Team, ITN Assessment Group or by an independent investigator, will be subject to review by the ITN Central Institutional Review Board (IRB). Benaroya Research Institute serves at the Central IRB for all ITN ancillary sample requests.

3.0 Contact Information

Sample requests should be sent to:

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