



TrialShare Sample / Data Request

INSTRUCTIONS:

The process for requesting ITN samples or data is centralized through the ITN Office of Sponsored Research and Planning (OSRP) within the ITN Coordinating Center. To request samples or data from ITN clinical trials, please complete this form and attach any supporting materials. Completed forms should be submitted to submissions@immunetolerance.org

To ensure a streamlined and efficient review process, all requests for ITN samples and data must be submitted through the OSRP.

Please note that requests for ITN samples or data submitted by investigators located outside of the United States are subject to NIAID review and approval prior to the release of any samples or data.

SECTION 1: General Information

A. TITLE OF PROPOSED STUDY

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B. ITN CLINICAL STUDY FROM WHICH SAMPLES / DATA ARE REQUESTED

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C. PRINCIPAL INVESTIGATOR

Last Name	First Name	Middle Initial	Degrees <input type="checkbox"/> MD <input type="checkbox"/> PhD <input type="checkbox"/> Other: _____
Position/Title			

D. MAILING ADDRESS OF PRINCIPAL INVESTIGATOR

Institution		Department	
Street Address			
City	State/Province	Zip/Postal Code	Country
Office Telephone	Fax Number	E-Mail Address	

E. COLLABORATORS / CO-INVESTIGATORS

In the space below, list any Co-investigators or collaborators to be involved in this study. i.e. *John Doe, University of Immunology, clinical collaborator*

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SECTION 2: Research Information

A. ABSTRACT

Please provide a brief description of the proposed research, including its objectives, scientific rationale, significance, and methodology. In addition, describe the relevance of the proposed research to immune tolerance. If the research is not directly related to immune tolerance, please explain its scientific objectives and anticipated contribution to the field.

B. STUDY REQUIREMENTS

Please provide a summary of the resources required to conduct the proposed research. Be specific regarding the participant populations, study visits, and the types and quantities of samples, data, and/or study results requested. For sample requests, please include the number of samples required, cell counts, serum/plasma volumes, or other relevant specifications, as applicable. Please also indicate the minimum number of samples required to complete the proposed analyses. This information will assist the ITN in evaluating your request in the context of other approved, planned, and proposed studies and in determining the feasibility of fulfilling the request.

If you are requesting samples, data, or study results from multiple ITN trials, please identify each trial and specify the materials requested from each.

Finally, please indicate whether any proposed assays or analyses will be performed in your laboratory or through an ITN Core Facility.

C. BUDGET ESTIMATE

For proposals requesting financial support, please provide a preliminary budget estimate. Detailed budget information will be requested upon approval of the proposal.

SECTION 3: Additional Project Information

A. CONFLICT OF INTEREST DISCLOSURE

Please disclose any personal, professional, financial, or commercial interests that you or your collaborators have that may be relevant to the proposed research. Please provide details below.

B. INSTITUTIONAL REVIEW BOARD APPROVAL

All projects utilizing ITN samples or data must have appropriate Institutional Review Board (IRB) approval or an applicable IRB exemption. While most proposals involving ITN samples qualify for exempt status, the ITN Material Transfer Agreement (MTA), which must be executed prior to the release of samples or data, requires confirmation that the recipient has obtained the necessary IRB approval or exemption determination. The ITN reserves the right to request documentation of the IRB approval or exemption prior to releasing samples or data.

Please indicate whether this project has already received IRB approval or an exemption determination, or whether such approval or determination will be obtained prior to the receipt of any ITN samples or data.

C. SUPPORTING PUBLICATIONS

If applicable, please provide up to five (5) publications relevant to this request. The publications do not need to be authored by the Principal Investigator but should support, justify, or provide context for the proposed research. Please provide complete citations for each publication, including all authors, article title, journal name, volume, issue, page numbers (if applicable), and year of publication.

D. CONFIDENTIALITY AGREEMENT

By submitting this ITN Sample and Data Request Proposal, I acknowledge that all samples and data provided by the ITN are de-identified. I further acknowledge that any attempt to identify or re-identify individual research participants, or to request information that could reasonably be used to identify or re-identify a participant, is strictly prohibited.