POLICY DOCUMENTATION

Data Sharing Policy

Version 2.0
Updated: August 27, 2019

What is covered in this document

This document includes ITN policies for when and how clinical, specimen and mechanistic study data will be released to the public, including how such release will be limited to protect participant privacy. The ITN TrialShare web portal is the primary mechanism of data sharing and therefore the main focus of this policy.

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 Sample Sharing Policy available at
https://www.immunetolerance.org/ITN_Sample_Sharing_Policy.pdf

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

Collaborations between ITN and individual investigators or partner organizations.

Table of Contents

Abbreviations

ITN – Immune Tolerance Network

NEC – Network Executive Committee

NIH – National Institutes of Health

PII – Personally Identifiable Information

PHI – Protected Health Information

1.0 Goals and Scope of this Policy

1.1 Policy Goals

This Policy aims to:

- Provide guidelines for the development of specific procedures for data sharing via ITN TrialShare, including creation and maintenance of publically viewable studies in the system
- Establish criteria for presenting study data and analyses on ITN TrialShare
- Encourage timely and appropriate use of ITN TrialShare to facilitate collaboration and dissemination of research data and results from ITN studies

1.2 Scope

This policy applies to sharing of ITN clinical, specimen and mechanistic study data, including the criteria and expected timing for release of such data and the de-identification required. Data release is accomplished by making the data publically available via the ITN TrialShare web portal. Loading of non-public operational data for use by ITN staff and collaborators is not within the scope of this policy. (See Reference 3.2 ITN TrialShare Data Access and Usage Policy for policies relating to user access to operational studies.)

The guidelines for timing of public data release listed in this document will be followed by ITN for all studies as closely as possible based on available resources and volume of data to be released. In all cases, if the study investigators and the ITN Network Executive Committee agree, data may be released sooner than the guidelines provided in this document.

2.0 Guiding Principles

2.1 Open Access Policy

The ITN subscribes to the principles of open access to scientific research, as documented in the Bethesda Statement on Open Access (http://www.earlham.edu/~peters/fos/bethesda.htm). As an NIH-funded entity, ITN follows the NIH Data Sharing Policy and Implementation Guidance (http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm). Furthermore, manuscripts arising from ITN-sponsored research are subject to the National Institutes of Health (NIH) Open Access Policy, which may be found at http://publicaccess.nih.gov/.

2.2 Participant Privacy Protection

ITN is committed to ensuring the privacy of participants in its clinical trials. ITN TrialShare is operated in accordance with the *Health Insurance Portability and Accountability Act* of 1996 (*HIPAA*) Privacy Rule (http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html).

2.3 Publications Policy

All categories of ITN manuscripts and case reports developed using ITN study data and/or analyses on ITN TrialShare are subject to the review process described in the ITN Publications Policy and Procedures available at http://www.immunetolerance.org/PublicationsPolicy.

2.4 Policy Oversight

The Network Executive Committee (NEC) acts as the primary decision-making body overseeing ITN policy. Changes or alterations to ITN policy are subject to ratification by the NEC.

3.0 Additional References

3.1 ITN TrialShare User Guide

The user guide available at https://www.itntrialshare.org/files/home/%40files/guides/UserGuide.pdf provides an overview of system functionality and use.

3.2 ITN TrialShare Terms of Use

The terms of use available at https://www.itntrialshare.org/tsstatic/Terms%20Of%20Use.html describes the responsible use individuals must agree to before accessing the system.

3.3 ITN TrialShare Data Access and Usage Policy

The user access and usage policy available at

https://www.immunetolerance.org/ITN_TrialShare_Access_Use_Policy.pdf describes ITN policies for providing user access to operational (non-public) study data.

3.4 ITN Sample Sharing Policy

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

4.0 Specimen Repository Data

Information about the inventory of specimens collected for a study that are remaining in the ITN bio-repository will be released 18 months after the Last Patient Last Visit for the study.

5.0 Manuscript Review

5.1 For certain manuscripts ITN may utilize TrialShare to supply journal reviewers with supplemental data, analyses, documentation and tools for exploring alternative analytic approaches to the manuscript submitted for review.

5.2 This Manuscript Reviewer version of a study will only include data and analyses related to the submitted manuscript. This may include raw and derived clinical and mechanistic data, laboratory result files such as flow cytometry fcs files, and images such as liver pathology. Specimen data will not be included. All data included in this version of a study will be de-identified. (See section 9 for details of the data de-identification process.)

5.3 Journal reviewers will be provided pre-created anonymous accounts with access to the specific manuscript in review.

5.4 Once a manuscript is no longer in review this version of the study will no longer be available.

6.0 Published Manuscripts

6.1 Contents

When ITN manuscripts are published, associated data and analyses will be made publically available in TrialShare. This includes all the clinical and mechanistic analysis datasets used in manuscript analyses. When possible and resources permitting, manuscript figures, the code base for figures and mechanistic analyses, and raw files such as FCS and CELL files will also be included. If the related study is not yet fully public then a version of the study containing only manuscript related data will be utilized for this purpose. All data released to the public will be de-identified. (See section 9.)

6.2 Timelines

If the publication contains a URL link to TrialShare then the manuscript related material will be released either on the day of the publication, or if requested by the publishing journal, several days in advance of the journal publication. For manuscripts without a URL included, data will be posted as soon as practicable, no later than 3 months after publication.

7.0 Remaining Clinical Data

(Not released as part of a published manuscript)

7.1 Contents

When a study is made fully public all available clinical analysis datasets will be released. If no analysis datasets are available then raw clinical data will be released, otherwise raw data will not normally be posted.

7.2 Timelines

Before a fully public version of a study can be released the study must be closed, the clinical database locked, and final Clinical Study Report (CSR) completed and signed off. Unless the primary publication for the study is in process, the fully public version of the study will be released approximately 18 months after CSR sign off. If a primary

manuscript is in process, release will be postponed until publication. Negative data may be released without prior publication.

8.0 Remaining Mechanistic Data

(Not released as part of a published manuscript)

8.1 "Core" datasets

"Core" datasets are those that are specified in the protocol mechanistic assay plan, using standardized methodology and reporting, such as microarray and flow cytometry data. These mechanistic assay result data will be released to the public 18 months after the final run date for the assay or in parallel with the remaining clinical data (approximately 18 months after CSR sign off), whichever is longer.

8.2 "Ancillary" datasets

"Ancillary" datasets are all other mechanistic assay results data. Release of these datasets will be approved by the ITN NEC on a case by case basis.

9.0 Participant Privacy Protection

9.1 Privacy Protection Plan

Prior to public release of a study, a Participant Privacy Protection Plan will be developed for each study and reviewed and approved by at least two members of the ITN executive leadership. The purpose of this plan is to ensure that the data, reports, files and all other materials associated with the study in ITN TrialShare comply with all HIPAA regulations regarding the disclosure of patient information. The plan will specify the datasets to be included in the public study, and will include a data dictionary providing the action to be taken on each individual data field. The plan will follow the Safe Harbor Method principles outlined by the U.S. Department of Health and Human Services (see reference 7.1.2). This includes removing or masking all Personally Identifiable Information (PII) and Protected Health Information (PHI). Additional criteria include:

Mask participant IDs

Shift or drop all dates with the exception of data management and system administration dates such as date of data cut

Round any ages >89 to 90

Remove site names, and remove or mask site codes for studies with <5 participants per site

Remove free text fields which might include unmasked participant IDs, dates or PHI. This will include all comment fields, verbatim terms, and free text reason fields; but need not include fields with negligible risk such as laboratory value units, medication names, and deviation codes.

9.2 Informed Consent Review

In addition to de-identification of data, ITN will review all the site-specific Informed Consent documents available for any participant privacy protection issues which may prohibit public release of de-identified study data. If evidence of informed consent cannot be obtained, individual level data on those participants will not be included in public versions of the study.

10.0 Revision History

Date	Version	Changes	Author
8/27/2019	2.0	Update URL links	Olivia Doyle