

POLICY DOCUMENTATION



TrialShare Access and Usage Policy

Version 1.2

Updated: July 15, 2013

What is covered in this document

- User access to the ITN TrialShare system
- User access to study data within ITN TrialShare
- User responsibilities regarding use of data obtained from ITN TrialShare

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/itn/Terms%20Of%20Use.html>

ITN Sample Sharing Policy available at
<http://www.immunetolerance.org/sites/files/ITN%20Sample%20Sharing%20Policy%20v2%2020130724.pdf>

ITN Data Sharing Policy available at
<http://www.immunetolerance.org/sites/files/ITN%20Data%20Sharing%20Policy%20v1.0%2020130724.pdf>

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Abbreviations

AD – Active Directory

ITN TrialShare Access and Usage Policy

ITN – Immune Tolerance Network

NEC – Network Executive Committee

NIAID – National Institute of Allergy and Infectious Diseases

NIH – National Institutes of Health

PI – Principal Investigator

PII – Personally Identifiable Information

PHI – Protected Health Information

SDCC – Statistics and Data Coordinating Center (such as Rho, Inc.)

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 ITN TrialShare user account management, including the account and study access request process
- Encourage appropriate use of ITN TrialShare to facilitate collaboration and the rapid dissemination of research data and results from Immune Tolerance Network (ITN) studies

1.2 Scope

ITN TrialShare is a web portal application enabling data sharing, scientific collaboration, analysis, and follow-up experimental design. This policy applies to ITN TrialShare and integrated systems. It covers user access to the system and the study data within the system.

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 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

The ITN manuscript review process is 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 Network Executive Committee (NEC).

3.0 Additional References

3.1 ITN TrialShare User Guide

The user guide available at <https://www.itntrialshare.org/itn/UserGuide/TrialShare%20User%20Guide.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/itn/Terms%20Of%20Use.html> describes the responsible use individuals must agree to before accessing the system.

3.3 ITN TrialShare Privacy Policy

The privacy policy available at https://www.itntrialshare.org/itn/privacy.html?_dc=20130430 covers TrialShare user privacy.

3.4 ITN Specimen Sharing Policy

<http://www.immunetolerance.org/sites/files/ITN%20Sample%20Sharing%20Policy%20v2%2020130724.pdf>

3.5 ITN Data Sharing Policy

<http://www.immunetolerance.org/sites/files/ITN%20Sample%20Sharing%20Policy%20v2%2020130724.pdf>

4.0 User Accounts and Access

4.1 Internal vs. External User Definitions

4.1.1 Internal Users

Internal users include all ITN staff.

4.1.2 Collaborators

Collaborators include staff from National Institute of Allergy and Infectious Diseases (NIAID), the Statistics and Data Coordinating Center (SDCC) and members of other organizations directly affiliated with studies in ITN TrialShare. Protocol Chairs, Site Principal Investigators (PIs), and their designated study support staff are also considered ITN collaborators.

4.1.3 External Users

External users are any users who do not fall into the categories of Internal Users or Collaborators.

4.2 User Account Creation

4.2.1 Internal Users

By default internal users may obtain ITN TrialShare accounts upon request without special approval.

4.2.2 Collaborators

Collaborator accounts must be approved by a senior member of the ITN leadership, e.g. the Network Director, a Network Deputy Director, an Executive Director, or the Senior Director of Bioinformatics. These approvals may be done in aggregate. These users may also be given accounts by default without prior request. In this case they will be notified of the account creation by email.

4.2.3 External Users

External user accounts may be requested or created without prior approval. This type of user account will only have access to publicly released study data that are available in the system. These users may request approval to become collaborators as above in 4.2.2.

4.2.4 Reviewer Users

Reviewer user accounts are a specialized type of account used exclusively by journal reviewers to access data and reports associated with manuscripts that have been submitted for publication. These accounts only have read access to the specific manuscript data in question for the period of the review. They are created as anonymous accounts (no real names or email addresses included) and the login information is provided to the reviewers along with the manuscript submission.

4.3 User Account Deactivation

4.3.1 Internal Users

Internal user accounts will be deactivated promptly if the user no longer meets the criteria of an internal user. This will normally be addressed through the standard IT process of removing former employees from the ITN Active Directory (AD).

4.3.2 Collaborators

Collaborator accounts will be deactivated promptly if the user no longer meets the criteria of a collaborator. If the collaborator has an Active Directory (AD) account then this will normally be addressed through the standard IT process of account deactivation. If the account was not AD, then the account must be deactivated by the ITN TrialShare support team. Accordingly, collaborators will be encouraged to notify the ITN TrialShare support team in advance of such events, or as soon as possible. In addition, the protocol chair or designated ITN staff member for the applicable study will review the list of collaborators (supplied by a TrialShare administrator) approximately quarterly and notify the administrator if any of the accounts should be deactivated. Finally, collaborator accounts will be deactivated after one year of inactivity, after which the user must request reactivation and be re-approved.

4.3.3 External Users

External user accounts will be deactivated after one year of inactivity, after which the user must reactivate the account.

4.3.4 Reviewer Users

Reviewer user accounts are de-activated once the review process is complete.

4.4 Access Level Definitions

See the ITN TrialShare User Guide

(<https://www.itntrialshare.org/itn/UserGuide/TrialShare%20User%20Guide.pdf>) for details of different access levels. Below is a general overview of the major groups sufficient for explaining the broad policy decisions herein. Note that access level may be different for the same user for different studies.

4.4.1 Reader

Readers can view all the data, reports and public postings associated with a study to which they have access; download data; and create their own reports to which only they have access.

4.4.2 Author

Authors have Reader level access, plus the ability to post comments and reports publicly.

4.4.3 Administrator

Administrators have access to every resource on the site. This is limited to members of the ITN TrialShare development team.

4.5 User Access

4.5.1 Authorized Internal Users

Internal users will generally be granted Reader access to all studies in which they have some level of involvement, and Author access to studies on which they

regularly work. The following access may be granted by default. Any additional access must be approved by a senior member of the ITN staff.

- Biologists and Clinical Trial Physicians: Author for all operational studies
- Operations staff: Author for studies in their therapeutic area(s), Reader in all others
- Bioinformatics staff: Author for all studies
- System administrators and trouble shooters may be designated by the Senior Director of Bioinformatics

4.5.2 Collaborators

Collaborators will be granted Reader access to all publicly released study data and to internally released studies in which they are an investigator, medical or scientific consultant, research assay provider, or otherwise directly involved in the study. In addition, collaborators who are Protocol Chairs and SDCC staff will be granted Author access to their studies, and ITN specialty cores may be granted Author access to all studies.

4.5.3 External Users

External users will be granted Reader access to publicly released study data.

4.5.4 Reviewer Users

Reviewer users will be granted Reader access study data associated with the manuscript submission to be reviewed.

5.0 User Responsibility

Regardless of whether a study is Internal or Public, it is the policy of ITN that end users shall utilize the system lawfully and not post any Personally Identifiable Information (PII) or Protected Health Information (PHI) to ITN TrialShare in forums or via any other means. Furthermore, users must also agree not to attempt to individually identify study participants using any information available on ITN TrialShare. These requirements are outlined in the Terms of Use.

6.0 Links and Integration

ITN TrialShare may include links to external tools, applications, websites, portals, or other products. These may be integrated with ITN TrialShare as appropriate. While ITN will make reasonable efforts to vet such links and integration, ITN will not assume responsibility for their content or functionality.

7.0 Authorship and ITN Acknowledgement

All categories of ITN manuscripts and case reports developed using ITN TrialShare are subject to the review process described in the ITN Publications Policy and Procedures (<http://www.immunetolerance.org/PublicationsPolicy>). All individuals meeting the requirements for authorship as set forth in the authorship guidelines of the International Committee of Medical Journal Editors 'Uniform Requirements for Manuscripts Submitted to Biomedical Journals' (<http://www.icmje.org>) must be listed as authors. All primary, secondary, tertiary and ancillary manuscripts must contain an ITN acknowledgement section as dictated in the ITN Publication Policy and Procedure. These requirements are outlined in the ITN TrialShare Terms of Use to which users must agree before accessing the system.

8.0 Revision History

Date	Version	Changes	Author
16Aug2012	1.1	Changed 'protocol' to 'study' where appropriate. Added section 7.0 on published studies. Modified wording to allow for automatic creation of public accounts. Removed requirements for PI and NIAID approval for making study data public. Added Reviewer accounts.	Tanya Antonille
14Apr2013	1.2	Removed content related to data sharing, operational and public data release. Removed default Author access by all ITN staff. Elaborated on requirements for collaborator access to a non-public study. Removed references to DMG.	Tanya Antonille