USIDNET Registry Principal Investigator (PI) Agreement

Name and Title of Principal Investigator (One PI is to be designated at each enrolling site)	
Name of Reporting Institution or Medical Practice	
Department	
Address	
Name of Institutional Review Board	
Phone number(s)	
Fax number	
E-Mail	

USIDNET Online Registry User Agreement

The United States Immunodeficiency Network (USIDNET) has established an online database system for research purposes for the collection and exchange of data on patients with primary immune deficiency diseases. The design, realization and maintenance of this online database ("USIDNET Online Database") is supported by DAIT/NIAID/NIH. The Principal Investigator (PI) intends to participate in the USIDNET Online Database system by providing data on patients diagnosed with primary immunodeficiency diseases.

By signing this Agreement, I agree to the following terms and conditions:

Data submitted to the USIDNET Online Immunodeficiency Patient Registry/Database shall belong to USIDNET for the purpose of gaining greater insight into and understanding of the primary immunodeficiency diseases through analytic research and clinical trials of diagnostic and therapeutic interventions.

1. The PI agrees to observe U.S. Government (HIPAA) patient data protection regulations as well as the patient data protection regulations applicable at its location as defined by the local Institutional Review Board (IRB). In particular, the PI shall acquire the necessary informed consent of the patients regarding the use of the data as stipulated hereunder. The PI acknowledges that he/she is responsible to ensure the observance of all local data protection regulations. In addition, all authorized users of the USIDNET Online Registry agree not to disclose the contents of the database to any unauthorized third party.
2. USIDNET has developed a clinical protocol and associated informed consent documents that have been reviewed and approved by Advarra IRB. These documents can be used as boilerplate templates for submission to PI's local IRB for approval, and can be found at the USIDNET website at **www.usidnet.org**.
3. USIDNET is responsible for implementing the technical and organizational measures required to ensure the highest level of security for the storage and processing of the Personal Health Information (PHI) contained in the Registry. The relevant information is available in the Clinical Protocol approved by Advarra IRB and posted on the USIDNET Registry website.
4. All requests for access to the database for any purpose require the submission of a Request for Query. All Queries are reviewed by the USIDNET Steering Committee. See accompanying **USIDNET Data Use Policy** for query regulations and guidelines, and **USIDNET Publication Policy** for publication guidelines. Browsing the data in the Registry will not be possible. Please keep in mind that every query is reviewed, and in some cases revisions are needed in order to clarify the request.

5. The investigator entering patient data shall have the opportunity to allow enrolling patients to choose to enter identified data in both (a) and (b) below, or only the minimal identifying data (b) set if preferred:
    a. Set 1 Full patient identifier information:
        i. Full Name
        ii. Full Date of Birth
        iii. Diagnosis
    b. Set 2 Mandatory minimum patient information:
        i. State of Birth
        ii. Year of Birth
        iii. Gender
        iv. Diagnosis
        v. State of Residence
        vi. Physician ID

Documentation of any change of PI at an institution must be made promptly by informing the USIDNET Registry Manager, at contact@usidnet.org. Either USIDNET or the enrolling site PI may terminate this agreement by giving written notice to the other party. The PI acknowledges that after the termination of this agreement, USIDNET shall be entitled to continue to use the data that have been provided to the USIDNET Registry Database up until the date of termination.

This agreement shall be governed by laws of the State of Maryland and the District Court of Maryland shall be the exclusive venue for all disputes arising out of or in connection with the present agreement.

Please read and then initial each statement below.

_____ As the Principal Investigator at my site I certify that local IRB approval has been obtained and will be renewed to keep current as long as my institution is participating in USIDNET Registry Enrollment.

_____ As the Principal Investigator at my site I certify that I have read and understand the USIDNET Data Use Policy and the USIDNET Publication Policy.

Please sign and date below.

_____ ___/___/_____

Principal Investigator Date

110 WEST ROAD ● SUITE 300 ● TOWSON, MD 21204 ● 800.296.4433 ● FAX 410.321.9165
www.primaryimmune.org ● www.usidnet.org

USIDNET Data Use Policy

Introduction

USIDNET is a resource for clinical insight into all primary immunodeficiency diseases. We encourage those who wish to learn more about these conditions to submit a query through our online submission system. Please keep in mind that every query is reviewed, and in some cases we ask for revisions in order to clarify the request. In order to ensure that your query is processed in the most efficient manner, we would like requesters to be aware of the following:

Longitudinal Data

At the present time, USIDNET does not have an abundance of chronological patient data to provide reliable longitudinal analysis of disease. Please keep this in mind when considering queries that are exploring immune deficiency in this manner.

Incidence / Prevalence

USIDNET is a patient-consented research study. It does not encompass all individuals in the United States with a primary immunodeficiency disease. Therefore, the USIDNET registry cannot be used to form conclusions on incidence or prevalence of any primary immunodeficiency diseases.

Requests to Use Data

USIDNET will release the clinical data necessary to successfully satisfy a discrete research question. Each query submitted must be justified by a research initiative, question or hypothesis. USIDNET does not release unlimited clinical information contained within the registry for the purposes of data mining or general review. All queries are reviewed by the USIDNET Steering Committee, and where applicable the pertinent Disease Specific Working Group, to determine whether the fields requested are reasonable and pertinent to the research question presented.

Other uses of USIDNET data can be arranged at the discretion of the Steering Committee, keeping in mind that ultimate use of the data must benefit patients with primary immune deficiency.

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USIDNET Publication Policy

Intent to Publish: Notification to USIDNET

(Prior to Submission)

Before submitting an abstract or manuscript for an investigation using registry data, it needs to be reviewed by USIDNET. Send your abstract or manuscript by email to USIDNET at contact@usidnet.org. Please include your intended date of submission, and the meeting or journal to which you plan to submit. We ask that you send submissions at least 2 weeks before the intended submission date. The USIDNET Steering Committee will review the abstract or manuscript, and in some cases may wish to add additional comments or suggest changes based on the nature of the data and the types of conclusions that can be drawn prior to submission. Additionally, USIDNET may request to re-review the abstract or manuscript after any changes are requested.

If you are planning a presentation that did not include an abstract submission, please send your slides for review.

Consortium Acknowledgment

When data in the USIDNET Registry is used in any manner in publications, abstracts, meeting materials, or other forms released to the public, please cite USIDNET with the following language:

> *The U.S. Immunodeficiency Network (USIDNET), a program of the Immune Deficiency Foundation (IDF), is supported by a cooperative agreement, U24AI86837, from the National Institute of Allergy and Infectious Diseases (NIAID).*

Authorship

USIDNET asks that you offer authorship to any enrolling physician who contributed 10% or more of the patients to the dataset you used in your work. If fewer than 5 physicians contributed 10% or more of the patients, we ask that you include the top 5 enrolling physicians. From there, you are encouraged to offer authorship to anyone else on the list of contributors who you feel contributed significantly to your work.

Additionally, if it works within the authorship guidelines for your target journal, we request that you include "The USIDNET Consortium" as an author, footnoted to include the remaining contributing physicians.