

## USIDNET Online Registry User Agreement

Name and Title of Primary Investigator	
Name of Reporting Institution or Medical Practice	
Department	
Address	
Name of Institutional Review Board	
Phone number(s)	
Fax number	
E-Mail	

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 Primary 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 become the property of NIH/NIAID and shall be used by NIAID &/or its assignees 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) or the Western Investigational Review Board (WIRB). 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. In the event that a reporting investigator does not have a local Institutional Review Board to oversee the conduct of clinical research, USIDNET has developed a clinical protocol and associated informed consent documents that have been reviewed and approved by the Western Institutional Review Board (WIRB). These documents are available for use by such investigators or institutions and can be found at the USIDNET website at [www.usidnet.org](http://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 the WIRB 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. If the USIDNET Registry Review Committee approves the request, the USIDNET Project Manager will prepare a query of the database and forward the results to the requesting Institution or Investigator. Browsing the data in the Registry will not be possible. As soon as the final report by the Database Manager is accepted by the requesting investigator or Institution, that report will be posted on the USIDNET Registry website. Academic investigators wishing to prepare a manuscript for a peer-reviewed scientific publication may request an embargo of such posting for a period not to exceed 12 months to permit the peer-review process to be completed and publication to be realized.

5. All users agree that if a reporting investigator's patient or patients are used in any report or publication based on data contained in the Registry that they will be acknowledged for their contribution by the authors of the report. Further it is agreed that all investigators who contribute at least 10% of the patients used in any report based on Registry data will be offered co-authorship of such reports. If several independent investigators located at a particular institution each have contributed patients to the Registry and if that institution should qualify for co-authorship, it is up to the investigators involved to decide who shall become a co-author if their contributions independently would not have qualified the individuals for co-authorship. Additionally, the user agrees to acknowledge the USIDNET Primary Immunodeficiency Patient Registry in any publications or presentations that use data obtained from the Registry database and a copy of all manuscripts shall be provided to USIDNET prior to submission. Manuscripts can be sent to [Contact@USIDNET.org](mailto:Contact@USIDNET.org).
6. The PI of a specific Institution may ask different persons from its organization to register as users of the USIDNET Registry by submitting a USIDNET Online Registry User Name and Password Application. The password will enable enrolment and grant access to the data provided by that investigator or institution. The PI shall guarantee that the user names and passwords are treated with absolute confidentiality and are not used for any other purposes than those defined herein. The PI shall immediately inform USIDNET about any unauthorized disclosure of the user names and / or passwords of the users of his/her organization as well as about the expiration of the right of single users within its organization to use the USIDNET Registry. The PI shall be responsible for the observance of all terms and conditions hereunder by all users of the USIDNET Registry for whom they co-sign a User Name and Password Application.
7. With the USIDNET Registry, USIDNET offers a forum only for data collection and/or data exchange and does not assume any liability for the efficient functionality and usability of the USIDNET Online Database, the integrity and/or usability of the data therein or the grant of access rights to third parties.
8. The PI shall have the opportunity to choose a minimal identifying data set if preferred:
  - a. Set 1 Mandatory minimum patient information:
    - 1 Full Name
    - 2 Full Date of Birth
    - 3 Diagnosis
  - b. Set 2 Mandatory minimum patient information:
    - 1 State of Birth
    - 2 Year of Birth
    - 3 Gender
    - 4 Diagnosis
    - 5 State of Residence
    - 6 Physician ID

Either party may terminate this agreement by giving written notice to the other party. The PI acknowledges that after the termination of this agreement, USIDNET shall on the conditions as stipulated hereunder be entitled to continue to use the data which have been provided to the USIDNET Online Database before 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.

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Date

Signature: Primary Investigator of the Reporting Institution

Please send the signed agreement to:  
USIDNET Registry Manager, c/o Immune Deficiency Foundation,  
40 W Chesapeake Ave, Suite 308, Towson, MD 21204  
FAX 410-321-0293  
[Register@USIDNET.org](mailto:Register@USIDNET.org)

June, 2008