
**WEST VIRGINIA
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE**

(6.4) Database User Accounts

Overview

The West Virginia Clinical & Translational Science Institute (WVCTSI) supports investigators' needs for approved access to databases containing patient data for purposes of conducting clinical and translational research. Access to this information requires additional permissions.

Purpose

The purpose of this policy is to identify the procedure by which anyone supported by WVCTSI or affiliated with WVCTSI must follow to apply for and maintain database user accounts.

Scope

This policy applies to all members of the WVCTSI and those who wish to utilize databases managed by the Institute.

Definitions

Integrated Data Repository (IDR) - one centralized database that brings together clinical information from sources around the state of West Virginia. As of April 2018, WVU Medicine is the only WVCTSI partner contributing data to the IDR.

Integrated Data Repository Web Portal – user interface of the centralized database that brings together clinical information from sources around the state of West Virginia.

TriNetX – global health research network that enables healthcare organizations, biopharma and contract research organizations to accelerate the clinical trial design and trial participant recruitment process

WVCTSI Members – individuals who complete the official membership form to gain access to services and resources provided by WVCTSI

WVCTSI Data Enclave - a solution implemented in 2017 that enables users to connect and analyze the data on their computer while keeping the data securely located within the WVU Health Sciences Center Data Center.

Policy

Those requesting data through the Integrated Data Repository and TriNetX must be WVCTSI members. IDR data is available to those members from institutions that contribute patient data to the IDR. WVCTSI membership and institutional affiliation will be verified before access to the database(s) will be granted.

Procedures

1. All applicants must be current WVCTSI members.
2. Users requesting IDR data must be primarily affiliated with an institution that contributes patient data to the IDR.
3. User accounts must be requested via the online form.
4. All usage of the IDR Web Portal and TriNetX applications is for scientific purposes only and aligned with the mission of the WVCTSI.
5. Before using any of the systems, the user must first login to the IDR Web Portal or iLab and accept the online user agreement. Terms are stated in the online agreement and if the user declines to accept the user agreement they will not be permitted to utilize the IDR Web Portal and TriNetX. Continued usage of any or all systems is contingent upon the user's continued acceptance of the terms stated in the user agreement.
6. If the user is no longer a member of the WVCTSI their user accounts will be terminated.
7. Data Requests will now come through iLab and data will be stored on the Data Enclave. Once the data request is completed and user agreement is accepted you can request accounts for the WVCTSI Data Enclave at (<https://wvuhsc.sharepoint.com/ctsivdi/SitePages/Home.aspx>).

Roles and Responsibilities

It is the role of the Biomedical Informatics staff to review requests and to verify WVCTSI membership and institutional affiliation of each person requesting access.

It is the responsibility of the user to follow HIPAA guidelines in addition to institutional IRB policies and procedures. It is also the responsibility of the user adhere to the user agreement provided upon account activation along with any subsequent updates.

The responsibility for interpretation of this policy rests with the Director of WVCTSI.

References and Authority

- Health Insurance Portability and Accountability Act (HIPAA):
<https://www.hhs.gov/hipaa/for-professionals/privacy/>
- Institutional IRB Policies and Procedures

Approval and Authority to Proceed

I approve the project as described above, and authorize to proceed.

| Name | Title | Date |
|---------------------|--|---------|
| Sally L. Hodder, MD | Director, West Virginia Clinical and Translational Science Institute | 4/10/18 |



4/10/18

Approved By

Date