(6.3) Integrated Data Repository Data Requests

Overview

The West Virginia Clinical and Translational Science Institute (WVCTSI) provides data to researchers, as well as a variety of services related to data management and analysis. Currently, data are pulled from clinical sites within the WVU Medicine system and stored in the Integrated Data Repository (IDR). Data may be requested to support clinical and translational research projects across disciplines. 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.

Purpose

The purpose of this standard operating procedure (SOP) is to provide a reference for the procedures and requirements related to the data services provided by the WVCTSI to ensure compliance with federal, state, and institutional data regulations.

Scope

This policy applies to anyone who wishes to request data from the WVCTSI. Those based at WVCTSI partner sites should also follow the procedures of their home institutions.

Definitions

BMIR—Biomedical Informatics team of the WVCTSI

Health Insurance Portability and Accountability Act (HIPAA)—Title I of HIPAA regulates the availability and breadth of group health plans and certain individual health insurance policies. Applicable to this policy and procedure, Title II of HIPAA defines policies, procedures and guidelines for maintaining the privacy and security of

individually identifiable health information as well as outlining numerous offenses relating to health care and sets civil and criminal penalties for violations. It also creates several programs to control fraud and abuse within the health care system

Integrated Data Repository (IDR) - one centralized database that brings together clinical information from sources around the state of West Virginia.

iLab—service request and management platform

IRB—Institutional Review Board. Administrative body that protects the rights and welfare of human research subjects at the affiliated institution(s)

PHI—Protected Health Information

Policy

All data requests must be submitted through iLab. Once a request has been submitted in iLab, it will be reviewed by a staff member for completeness and compliance with all WVCTSI and IRB policies before assignment to a member of the BMIR team. WVCTSI provides data strictly for research requests; quality improvement projects should be directed to hospital analytics. Project review by a biostatistician and/or epidemiologist prior to submission to BMIR is strongly recommended. All elements of Protected Health Information must be included on the approved HIPAA Waiver of Consent provided to BMIR. IDR data is available to only those members from institutions that contribute patient data to the IDR.

Procedures

1. Obtain the necessary IRB approval to conduct this research project. If a fully de-identified data set is requested, IRB approval is optional but strongly recommended. If a Preparatory to Research data set is requested, an IRB-approved Preparatory to Research form is required. If a data set containing any element of PHI is requested, an IRB approval letter and HIPAA Waiver of Consent are required. All paperwork should be provided to WVCTSI via the iLab data request form.
2. After obtaining IRB approval or exemption, and creating an iLab account, the data set may be requested via the following steps:
    a. Sign into iLab. From the home page, choose “List all cores” on the left side.
    b. From the list of cores, select the WVCTSI Clinical Research Design, Epidemiology, and Biostatistics Core. Since this is a closed core, users

may need to submit an access request. Access will be approved by a WVCTSI staff member within two business days.
    c. After receiving your core access approval email, if necessary, in the upper right hand corner of the core home page, click on the “Request Services” tab.
    d. Choose “request service” next to Bioinformatics Data Request.
    e. Complete the request form in full; then click “submit.
3. All personnel on a research project must be named on the approved IRB, and sign the WVCTSI Data Use and Confidentiality Agreement prior to receiving data. To sign the agreement:
    a. Sign into iLab. From the home page, choose “List all cores” on the left side.
    b. From the list of cores, select the WVCTSI Clinical Research Design, Epidemiology, and Biostatistics Core. Since this is a closed core, users may need to submit an access request. Access will be approved by a WVCTSI staff member. IDR data is available to those only 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.
    c. Investigators will be notified of Core access approval or denial by email.
    d. If access is approved, in the upper right hand corner of the core home page, click on the “Request Services” tab.
    e. Choose “request service” next to Data Use and Confidentiality User Agreement.
    f. Complete the request form in full; then click “submit.” After completion of this agreement, the requester will be permitted to receive data. Additionally, a TriNetX account will be created, and details on completing TriNetX account setup will be emailed. Currently only researchers at West Virginia University are eligible for TriNetX accounts.
4. Once the data set is completed, it will be delivered to the research team via the WVCTSI Data Enclave, a secure environment for data viewing and analysis. Any petitions to receive data in a format outside the WVCTSI Data Enclave must be reviewed and approved by the Data Governance Committee.

Roles and Responsibilities

It is the responsibility of the requestor and research team to obtain and maintain appropriate IRB approval and provide all necessary documents and information to WVCTSI. WVCTSI reserves the right to request additional information at any time to clarify project details and aid the request process. 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 to 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 procedure 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