

WVU Research Data Protection Certificate

High Risk

Certificate# 0254

Keep this document with your project records. Attach this document to the protocol submission and provide it for Data Use Agreements. The protection requirements for the data associated with your project are provided below. The implementation and adherence to the requirements are the responsibility of the Principal Investigator. If the data requirements change for the project, a new Data Protection Request form must be completed by the PI.

General Information

Research Project Title: Test long titleTest long titleTest long titleTest long titleTest long titleTest long

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Principal Investigator: Louis Rovegno **Department:** Aerospace Studies

Date of Certification: 09/09/2021

WVU HIPAA Covered Entity: Yes
Medical Record Access: No
International Components: Yes

Data Sharing and Transfer (in/out of WVU Institutional Entities): Yes **All software is on the WVU Approved Technology for Research List:** Yes

New technology products or services needed for this project: Yes

Data Overview

Data Source: WVU HSC Approved Data/Biospecimen Repository

Data Type: PHI

Data Variables Selected:

Name, Admission Dates, Discharge Dates, Surgery or Procedure Dates, Medical Test Dates

Approved Data Plan:

WVU HSC Managed Network Server

- Encrypted secure file server location accessible on HSC internal network.
- Accessible onsite at HSC, and offsite via HSView to researchers with an HSC managed device offsite with HSC VPN and DLP.
- Student access available through Windows Terminal Server onsite or offsite.

This solution requires the following:

- WVU Login account.
- HSC managed encrypted desktop for faculty and staff.
- Windows Terminal Server for students.
- Additional cost for Data Loss Prevention (DLP) software for faculty and staff Requirement for sensitive data.
- For offsite use HSC VPN approval and setup is required.

Oncore / Advarra

Clinical Trial management system

This solution requires the following:

Requirements are based on CRU policies.

HSC Qualtrics

- Qualtrics is Health Information Trust Alliance (HITRUST) certified
- · Encryption of data in transit and at rest
- Offers survey security and sensitive data controls
- Accessible from an HSC managed device or HSView

The solution requires the following:

- Prior approval is required for each project before the WVU HSC HIPAA Qualtrics Brand may be used
 to create surveys for the collection of sensitive data. Approval from the Chair of the Department or
 Administrator of the unit is required.
- HIPAA data is only approved for storage in the WVU HSC HIPAA Qualtrics brand, not the WVU
 Qualtrics brand. Surveys that will collect health information may only be created in the WVU HSC
 HIPAA Compliant Qualtrics Brand and no other brand of Qualtrics.
- WVU Login account with MFA
- Users with access to the WVU HSC HIPAA Qualtrics Brand must only login from an HSC managed computer with DLP, or access via the HSC VDI environment (HSView)
- Additional cost for Data Loss Prevention (DLP) software for faculty and staff Requirement for sensitive data

For assistance with the above protection solution(s), Contact the HSC IT Service Desk at (304) 293-3631 or hsc.wvu.edu.

Data Agreement Overview

Data Agreement Needed: Yes

Current and Pending Agreements: No Data Use Agreement in place or pending, or unsure

Funding/Sponsor: Test Sponsor

Other Agreements/Policies/Restrictions: No

IRB of Record: WVU

Next Steps

- A HIPAA Waiver of Authorization is required for identifiable data. Request the waiver here.
- Submit your protocol to the IRB and attach this Data Protection Certificate.
- Once your protocol is approved/acknowledged, attach the approval letter to your <u>iLab request</u>.
- Discuss your data sharing requirements with the WVU Office of Sponsored Programs. OSP will contact you in 1-3 business days or you can contact them directly.
- If you indicated that the project requires unapproved software for data collection, participant communication, or payment, the appropriate support staff will contact you within 1-3 business days.