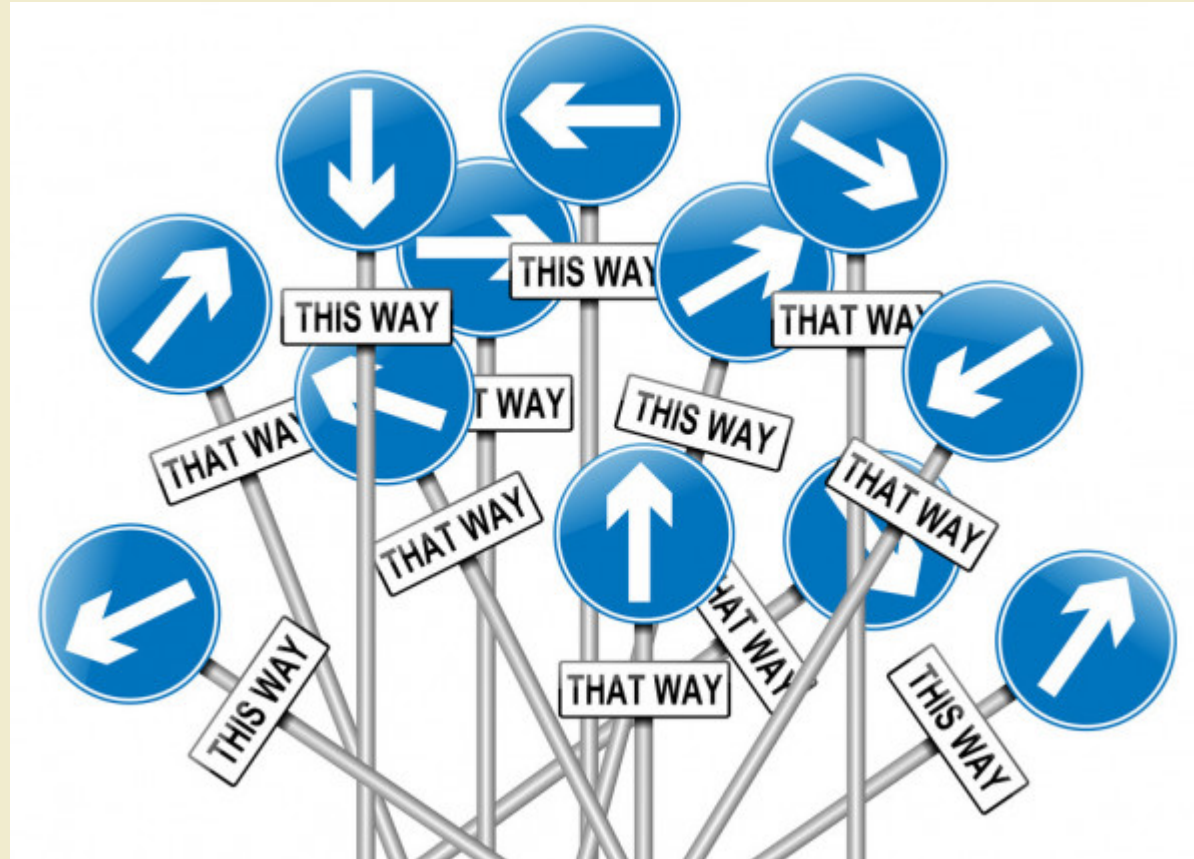


WVU RESEARCH DATA PROTECTION

SPONSORED BY :

THE WVU RESEARCH OFFICE, WVU ITS, HSC ITS, AND WVCTSI

CURRENT STATE



Unapproved Software

Data Storage Plans

International Components

Data Agreements

Sensitive Data

HIPAA Waivers

IMPACT – CURRENT STATE



Delays in protocols, agreements, and other approvals
Compliance risks for data storage and missed approvals for other research components
Ineffective use of everyone's time to review and determine who to call, etc.

WHAT DOES DATA PROTECTION DO FOR YOU?



SAVES TIME FOR EVERYONE

BENEFITS

HOW DP HELPS YOU

- ✓ **STREAMLINES** the approval processes for research – START with DATA PROTECTION then the Protocol, Data Agreement, etc.
- ✓ **DECREASES FRUSTRATION** of determining who to contact – THEY WILL CONTACT YOU!
- ✓ The WVU IRB can **FOCUS on HUMAN SUBJECT PROTECTIONS** rather than software approvals.
- ✓ OSP will be notified **EARLY** of Data Agreement requirements and can plan accordingly.
- ✓ CTSI will **BE AWARE** of the request before the iLab request is received.
- ✓ Other compliance items will be **addressed PROACTIVELY**.
- ✓ **EDUCATES** the researcher regarding the risk related to the data and regulatory/institutional requirements.

AUTOMATED FORM – ONE STOP FOR APPROVALS

PROVIDES AUTOMATED APPROVAL FOR DATA STORAGE PLAN

- Smart Form with automated workflow
- Routes to 7 departments depending on answers
- Auto approves ALL Low Risk Data Storage Plans
- Auto approves ALL Medium Risk Data Storage Plans

STARTS THE PROCESS FOR OTHER APPROVALS

- Routes to appropriate groups for approvals/discussion
- Routes to the Export Control Office for approvals/discussion
- Routes to OSP to initiate the Data Agreement process
- Routes approvals for participant payment and unapproved software

PROVIDES NEXT STEPS FOR THE RESEARCHER

- HIPAA Waiver
- Requesting Medical/Dental Data
- Other Approvals
- How to Begin with Storage, Purchases, etc.

REPLACES THE DATA INTAKE FORM

WHEN DO I NEED TO SUBMIT A DATA PROTECTION REQUEST FORM?

- 1. When sharing data in or out of the University/Affiliates**
- 2. When planning to submit an INITIAL IRB protocol**
- 3. In support of a Proposal submission**

DATA PROTECTION CERTIFICATE

WHAT IS IT? WHAT IS IT USED FOR?



❖ Attach to the INITIAL IRB Protocol Submission



❖ Provides a record of data requested and approvals



❖ Provide to OSP for Data Agreement requests



❖ The source for research personnel access for WVU medical/dental records requests

HOW LONG DOES IT TAKE TO GET A DATA PROTECTION CERTIFICATE?

Low Risk Data

WITHIN MINUTES if using the approved storage plans

What is Low Risk Data ?

- ❖ **Anonymous**
- ❖ **Fully De-identified** (the researcher never had access to the identity of the participant)
- ❖ **Data From Public Sources**
- ❖ **Data with No Identifiers**

HOW LONG DOES IT TAKE TO GET A DATA PROTECTION CERTIFICATE?

Medium Risk Data

WITHIN MINUTES if using the approved storage plans

What is Medium Risk Data?

- ❖ Data classified by the University as **Confidential**
- ❖ Research PII - The Data may include identifiers but HIPAA does not apply (non-covered entities)

HOW LONG DOES IT TAKE TO GET A DATA PROTECTION CERTIFICATE?

High Risk Data

No PHI – WITHIN MINUTES if using the approved storage plans
PHI - 2 to 5 Business Days if using the approved storage plans

What is High Risk Data?

- ❖ Data classified by the University as **Sensitive** which includes:
 - PHI (WVU Medical/Dental Records Access to Identifiers) Includes the MRN
 - A WVU Covered Entity Collecting PHI Identifiers from Participants (non-healthcare event)
 - Data from HSC Biospecimen repositories
 - Drivers License, Financial Information, Biometric Information (Refer to the **WVU Sensitive Data Policy**)

HOW LONG DOES IT TAKE TO GET A DATA PROTECTION CERTIFICATE?

Not using an approved storage plan?

- ❖ The following reviews may be required for hardware/software/services:
 - The Research Office
 - The ITS departments
 - WVU Information Security
- ❖ Can take 2-4 weeks for approval depending on the data risk and the request.

WVU Research Data Protection Certificate

Medium Risk

Certificate# 0289

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: Student Teacher Identity Development through Mentoring Dialogues
Principal Investigator: Angela Munroe
Department: Music
Date of Certification: 09/16/2021
WVU HIPAA Covered Entity: No
Medical Record Access: No
International Components: No
Data Sharing and Transfer (in/out of WVU Institutional Entities): No
All software is on the WVU Approved Technology for Research List: Yes
New technology products or services needed for this project: No

Data Overview

Data Source: Data Collection (Identifiable)

Data Type: Research PII

Data Variables Selected:

Name, Email Address, Full face photographic images and other comparable images, Business Email Address

Approved Data Plan:

APPROVED STORAGE/TECHNOLOGY FOR COLLECTION OF CONFIDENTIAL DATA

- Storage is permitted on:
 - University network drive (HSC or WVU)
 - Storage on Personal network drive (e.g., J:, N:, Y:)
 - University OneDrive or SharePoint
 - University-owned device
 - [WVU Research Data Depot](#) (minimal charge for use)
- Access to files must be limited to research project personnel only, with access regularly reviewed to remove personnel no longer on the project.
- Use of University Devices is required for employees. Students may use personal devices provided the device meets the requirements of the [Bring Your Own Device Standard](#).
- WVU Qualtrics, RedCAP, or HSC Qualtrics may be used for collection of information and/or electronic Informed Consent.

DEMO – DP REQUEST FORM

DATA PROTECTION REQUEST FORM

REQUIRED BEGINNING OCTOBER 11, 2021

The FIRST STEP for your project!

- ✓ ALL INITIAL Human Subjects Protocol Submissions (IRB)
- ✓ ALL Data Agreement Requests for OSP

The form and process can be used to make decisions during the Proposal phase.

QUESTIONS?

Guidance and Help

[Support Email: ResearchDataProtectionSupport@mail.wvu.edu](mailto:ResearchDataProtectionSupport@mail.wvu.edu)

[Website Site: Data Protection Process Support](#)

[Website: Research Office - Research Data Information](#)

THANKS FOR ATTENDING!