TECHNOLOGY
TEXAS WOMAN'S UNIVERSITY

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Data Management and Integrity in Human Research

Researchers must develop and follow protocols to manage and protect the security and integrity of participant data, particularly Protected Data (Confidential Data). This document provides practical recommendations to help TWU's researchers protect participant data.

So if I leave off the social security number, I'm ok, right?
Wrong. While the SSN should not be collected at all, each of these examples are PII and when multiple PII data are collected on a single participant, that person's personal information and security are at risk.

Types of Protected Data

Personally Identifiable Information (PII)

Personally Identifiable Information (PII) can be used on its own or with other information to identify, contact, or locate a single person, or to identify an individual in context. Examples include name, social security number, date and place of birth, mother's maiden name, or biometric records; and any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.

FERPA

Family Educational Rights and Privacy Act (FERPA) protects the privacy of student educational records. If you must collect student records through the Registrar, Colleague, a SQL report, or through some other method, you are expected to:

- Use the information only for purposes of the approved research project. Any new use of the information requires new approval.
- Provide adequate protection for the information to ensure that it is not compromised or subject to unauthorized access.
- Ensure that no one outside the research team has access to the information.
- Destroy the information within a reasonable time after completion of the research.

HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides comprehensive federal protection for the privacy of protected health information (PHI). Learn more at the NIH website. The Privacy Rule permits certain incidental uses and disclosures that occur as a by-product of another permissible or required use or disclosure, as long as the covered entity has applied reasonable safeguards and implemented the minimum necessary standard, where applicable, with respect to the primary use or disclosure. As best practice, researchers should protect PHI and electronic PHI (ePHI) by de-identifying data when possible.

Data Collection Guidelines

Researchers must comply with TWU's Office of Research & Sponsored Programs IRB Policies. Further, if the researcher is **videotaping/recording a classroom**, consent must be obtained from

everyone in the classroom or the camera must be situated so that there is no chance people who haven't signed a consent form are captured on the video or audio. This includes video and audio recording via web conferencing tools such as Zoom or Google Meet. See TWU's Information Security Web Conferencing Standard for additional details on protecting meeting and participant privacy.

If collecting data via an **online survey** (such as Qualtrics, PsychData), the researcher will likely be storing PII. As soon as data collection is complete, data should be exported and the survey and results removed from the survey website. As with all research data, we recommend both encryption and regular backup.

Data Management and Protection

Data management includes ownership, collection, storage, protection, retention, analysis, sharing, and reporting. **Data storage and protection** are critical aspects of human research data management. Proper data management includes protection.

The Office of Research Integrity (ORI) suggests protection is best ensured by **limiting** access to data, **protecting** the computer systems with an updated antivirus, and **encrypting** the data (ORI, Steneck 2007).

Guidelines for Human Research Data Storage and Protection

1. Data Management Plan. As you begin the research project, work with your fellow researchers to **discuss how data** will be collected, maintained, archived, and protected.

Once data are collected, these files are to be protected as they will likely contain PII, FERPA and/or ePHI info. We recommend assigning each participant a unique identifier which is not at all related to their Protected Data. This unique identifier could then be used in shared datasets to link the participants between the protected dataset and the shared datasets.

Unique identifiers can easily be created in Microsoft Excel. Import the data you need to share into Excel. Insert a column. Give it a title, like "Unique ID." Type in an alphanumeric string. For ease of use, the string should end in a number and the number should contain enough integers to account for the maximum participants expected in the study. To the right, you see the first UniqueID created is 1001. It could also be EX101 or any other string of characters ending in a multi-digit integer. Repeat the naming convention in the cell below, increasing the value of the string by one. *(If EX101, then EX102 below)* You can drag this single value down the column to create a non-repeating set of unique identifiers. Highlight both cells containing unique ID values. Place your cursor over the lower-right corner of the

	A	B	C	D	E	F
1	**UniqueID**	**InterviewDate**	**Q1**	**Q2**	**Q3**	**Q4**
2	1001	9/5/2013	0	0	2	7
3	1002	8/31/2013	1	0	0	3
4		9/2/2013	1	0	1	0
5		9/4/2013	1	2	4	8
6		8/31/2013	0	1	3	5
7		9/2/2013	1	1	0	5
8		9/6/2013	0	2	4	7
9						

bottom cell. A plus sign appears. Click and drag the plus sign down through your spreadsheet until all data have a unique ID.

	A	B	C
1	UniqueID	InterviewDate	Q1
2	1001	9/5/2013	0
3	1002	8/31/2013	1
4		9/2/2013	1
5		9/4/2013	1
6		8/31/2013	0
7		9/2/2013	1
8		9/6/2013	0

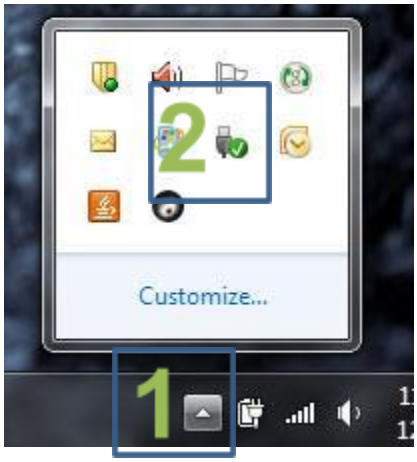
	A	B	C
1	UniqueID	InterviewDate	Q1
2	1001	9/5/2013	0
3	1002	8/31/2013	1
4	1003	9/2/2013	1
5	1004	9/4/2013	1
6	1005	8/31/2013	0
7	1006	9/2/2013	1
8	1007	9/6/2013	0

	A	B	C	D	E	F	G	H
1	UniqueID	InterviewDate	Q1	Q2	Q3	Q4		
2	1001	9/5/2013	0	0	2	7		
3	1002	8/31/2013	1	0	0	3		
4	1003	9/2/2013	1	0	1	0		
5	1004	9/4/2013	1	2	4	8		
6	1005	8/31/2013	0	1	3	5		
7	1006	9/2/2013	1	1	0	5		
8	1007	9/6/2013	0	2	4	7		
9								

Shared Data with Unique ID

Properly Ejecting a USB Drive

USB drives are notoriously unstable and can damage data on hard drives. Properly removing USB drives is essential to data protection.



1. Click the Show Hidden Icons button on your desktop tray (lower-right corner).
2. Select the Safely Remove USB Drive icon. Select your drive and remove.

2. Data Security. There are many schemes for securing data in a personal computer. The most secure method is to use a removable hard drive that resides in a safe or locked cabinet when not in use. To process data one simply installs the hard drive, disconnects all other storage devices (e.g. USB drives), disconnects the network, and then boots the computer to do processing. This procedure is very secure, but often impractical. When using a method such as this, researchers are responsible for creating their own backups and ensuring that the backup files are also secure and encrypted. Because this method of data storage is not often conducive to collaboration, many researchers may opt to use network storage or cloud storage options provided by TWU. Cloud storage is only recommended for de-identified data.

Minimal effort at data security is password protection. You can easily password protect SPSS files, Microsoft Office files, SAS files. Do not forget your password. Data are unrecoverable if the secure password is lost.

Encryption is the key to secure data and it is TWU's policy. Symmetric cryptosystem key lengths should be at least 128 bits for confidential data and other agency-sensitive information identified by TWU. Confidential or agency-sensitive information transmitted over the internet or as an email message must be encrypted.

There are many software solutions for encrypting data. For Windows, we recommend using BitLocker Drive Encryption. Need help encrypting files? Contact the TWU Service Desk.

Store physical data (either electronic devices - such as external hard drive, flash drive, DVD/CD - or paper hard copies) in an **area with key access**. Restrict key access to only necessary research personnel. It is the responsibility of the principal investigator to make the decision regarding the access to confidential research data and training the research personnel as required.

Video and audio recordings are data that should receive high-level security prior to de-identification. We recommend assuming these data contain PII and storing them in an area with key access (if physical recordings on audio/video devices) or on non-cloud storage (if collected via web conferencing platform) because a participant may share something personal on the recording such as medical history or a home address. Recordings may be uploaded to the cloud after the data have been de-identified.

3. Data Retention. Typically, research data must be retained **for at least 5 years** from the date of the most recent IRB approval. Retention requirements may vary by discipline, and any requirements stipulated in an IRB approval must be followed. The informed consent forms or the short form and the research summary must be retained by the investigator on behalf of the institution for at least 3 years unless it has been waived by the IRB (HHS).[1] We recommend storing two copies in separate, secure locations (ensuring a backup). **Identifiable data** (such as audio/video recordings) are recommended to be destroyed as soon as a transcribed copy has been created and backed up.

[1] If the investigator designated for the purpose leaves the institution, it is the responsibility of the institution to replace the investigator by a responsible representative for the research data management as suggested by the HHS. In addition, HHS also requires that the research data are secured in hard copy or soft copy format and be accessible for either inspection or copying purposes by authorized representatives of HHS.

4. Data Destruction. When appropriate, all data containing personal, medical, or educational record data should be properly and permanently deleted (see NIST Guidelines for Media Sanitization). Paper should be shredded in a cross-cut shredder; CDs and DVDs should also be processed through an industrial shredder. Portable hard drives, dedicated hard drives, and USB flash drives should be wiped using software; please contact the Service Desk for assistance.

5. Data Documentation. How are the data stored and backed up?

Storage Device	Advantages	Disadvantages
Paper Copies	Inexpensive Low Corruptibility	Susceptible to damage Difficult to share and manage data
USB Thumb / Flash Drive  **Removable Hard Drive** 	Ease of use Inexpensive	Questionable reliability Prone to corruption Not integrated well for backups Low read/write speed
TWU X Drive	Ease of use Accessibility No cost to students, faculty, staff Automatic backups	Only on-campus or VPN
Cloud Storage (such as Google Drive and Office 365)	Ease of use Accessibility Multiple users can access No cost to students, faculty, staff Automatic backups	Not recommended for research data unless data are de-identified as explained earlier in this document Intellectual property ownership concerns

USB drives can only be secured through encryption software. Any electronic files should be both encrypted and password protected. *The easier it is for you and your team to access the files, the easier it is for that data to be compromised.*

6. Planning for Data Disaster - Regularly Back Up Your Data

- Cloud storage provided by TWU (Google Drive and Office 365) are automatically backed up.
- X Drive network storage is backed up often by TWU IT Solutions.
- Regularly **back up your data** on an encrypted drive with a minimum 128-bit encryption algorithm (see how to encrypt a drive using BitLocker).

- Monitor the progress of research study or clinical investigations according to the approved protocols and the safety of participants. The **PI must assign the duty of regular monitoring of processes and reporting** and have communicated procedures to be followed by the personnel monitoring the process in cases of unanticipated situations or circumstances.
- Adhere to the policies and assure compliance regarding **unanticipated situations** and reporting the same to IRB. Quality control plans must be in place to respond appropriately.
- If the study requires a **temporary suspension or modification of protocol** in order to resolve unforeseen problems, a procedure must be established to first secure the data that were obtained. Then a decision can be made if the data should be discarded, considering possible implications of both data usage and destruction. A plan to this end must be included in the original protocol.
- Find additional **detailed information regarding data and safety management plans**.[2]

[2] For Phase I and II trials NIH does not require a data and safety management board, but for multi-site phase I and II studies, it does require investigators to keep reports of adverse events reported in a timely manner. For additional information refer to the NIH website http://grants.nih.gov/grants/guide/notice-files/not99-107.html)

FAQs

How do I know if a drive is secure?

Student researchers should contact the TWU Service Desk. They can discuss data security options with you. Faculty should contact TWU Office of Research & Sponsored Programs.

What if I store data on a flash drive?

While inexpensive and easy to use, flash drives are prone to corruption and difficult to back up. Use precaution and encrypt the drive, or choose an alternative storage method.

What if I collect data on a laptop?

TWU laptop assets are secure and data stored should be treated with the same protections as TWU desktop computers. When the laptop is not in use, it should be locked, password protected, and stored in a secure location.

What if I store data on Office 365 or Google Drive?

Cloud storage is useful for collaboration, but should not be used for sensitive data. It is recommended to de-identify data prior to storing data on the cloud. Files should be password protected, when possible.

How can I password protect a data file?

Here are some common research applications that offer password protection: SPSS files, Microsoft Office files, and SAS files.

Can I use my personally-owned device to collect research data? What if I collect data on an iPad or iPhone?
Per our Data Access and Use policy, University Data classified as Confidential Data must not be stored on a personally-owned computer, portable computer, personal digital assistant, or any other personally-owned single-user system. University data created and/or stored on personal computers, other devices and/or non-University databases should be transferred to University information resources as soon as feasible. In the event that personal devices are used, the device(s) should be encrypted and maintain the same patch/configuration standards as TWU assets. University data created or stored on users' personal computers, smart phones or other devices, or in databases that are not part of University's information resources, are subject to public information requests, subpoenas, court orders, litigation holds, discovery requests and other requirements applicable to the University.

What about if I email data files? Is that safe/okay?
Email is not secure. Do not use email for transmitting PII data.

What about video/audio recordings stored on a camera or audio recorder?
Recordings should be backed up for security purposes. Devices should be stored in a secure location. Recordings should be destroyed after de-identified transcriptions have been created.

Can I carry data storage devices out of my workplace?
This is not a recommended practice. Data are vulnerable, particularly when they are not in a secure location. You may carry devices out of the workplace if they are encrypted. Password protection alone is not enough.

Can I save personal information on research storage devices?
Your personal data should be stored separately from your research data.

I have a database connected to the internet. Is it secure?
Even an encrypted database can be at risk online. Files must be encrypted and password protected to assure security. A risk assessment from TWU Information Security is recommended; please contact the TWU Service Desk.

Can graduate students take their research data with them?
In most cases, research data will belong to the University.

I am traveling abroad. How should I access my data?
TWU IT Solutions will provide employees who plan to travel to foreign countries with laptops that meet all the criteria for the "tools of trade" exemption. Employees are required to complete the form on this page to arrange the loan of a clean laptop for trips abroad. [policy]