SOP: Storage of Identifiable Protected Health Information for Research				
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1 PURPOSE

1.1 The purpose of this standard operating procedure is to establish the requirements and processes to select a secure storage environment for research involving identifiable health information conducted at Virginia Tech.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 These requirements apply to research involving identifiable protected health information (PHI) or research health information (RHI) conducted at Virginia Tech. (See PRDP-001 Research Data Definitions for a description of PHI or RHI)

4 RESPONSIBILITIES

4.1 Researchers

4.1.1 The research team should be familiar with the regulatory requirements for their research and must obtain approval from the Virginia Tech Human Research Protection Program (HRPP) or Institutional Review Board (IRB), before initiating any human subjects research activities.

4.2 Privacy and Research Data Protection Program (PRDP)

4.2.1 The PRDP will coordinate with researchers and data storage administrators to streamline the review of data management plans and the data storage approval process to meet applicable international, federal, state, and university requirements.

5 PROCEDURE

5.1 If a researcher proposes to collect or obtain PHI or RHI that contains one or more participant identifiers, the researcher should contact PRDP (prdp@vt.edu) for guidance on the appropriate storage of the project data.

5.2 PRDP will evaluate the risk to participants associated with the data using the following information. If a protocol has been submitted to the IRB Protocol Management system the protocol number will provide the information below and no additional documentation will be required.

5.2.1 Project name

5.2.2 Project description (2-3 sentences describing the purpose, specific aims, or objectives of this study)

5.2.3 Principal investigator (PI)

5.2.4 Project data storage and privacy requirements (project storage, REDCap, other) and plans to meet privacy requirements.

5.2.5 Data Management Plan (this may be a standalone document or part of a protocol submitted to Protocol Management) and should include:

5.2.5.1 Data Type: A general summary of the types and estimated amount of participant related data to be generated and/or used in the research. (e.g., 256-channel EEG data and fMRI images from ~50 research participants). Descriptions may indicate the data modality (e.g., imaging, genomic, mobile, survey), level of aggregation (e.g., individual, aggregated, summarized), and/or the degree of data processing that has occurred (i.e., how raw or processed the data will be)

5.2.5.2 Related Tools, Software and/or Code: An indication of whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse, and name(s) of the needed tool(s) and software.

5.2.5.3 Standards: An indication of what standards will be applied to the scientific data and associated metadata (i.e., data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation).

5.2.5.4 Data Preservation, Access, and Associated Timelines: The name of the repository(ies) where the participant related data and the related metadata will be archived; who will have access to the data; and for how long

5.2.5.5 Access, Distribution, or Reuse Considerations: Describe any applicable factors affecting subsequent access, distribution, or reuse of scientific data related to whether access to scientific data derived from humans will be controlled (i.e., made available by a data repository only after approval).

5.2.5.6 Oversight of Data Management and Sharing: Indicate how compliance with the data management plan will be monitored and managed, frequency of oversight, and by whom (e.g., titles, roles).

5.2.6 PRDP will review the data management plan and ensure that it meets applicable regulatory requirements. Reviews will be completed within 5 working days of submission.

5.2.7 PRDP will support the PI in the remediation of any identified gaps in the data management plan.

5.2.8 Concurrent with the review of the data management plan, training on the use and protection of health information will be conducted as required.

5.2.9 Training may be taken through virtual PRDP presentations or an approved third-party vendor. If you have completed training on protected and research health information in the past 12 months, please contact PRDP (prdp@vt.edu) to determine if this training will meet this requirement.

5.2.10 For existing projects, new research team members can request training by emailing PRDP (prdp@vt.edu).

5.2.11 A certificate of completion will be generated by PRDP, and a copy will be retained by PRDP for three years. Training will need to be renewed every three (3) years.

5.3 PRDP will advise the researcher which of the available secure storage environments are best suited to the research project under review. PRPD will work with administrators of the selected storage environment to set up the project access.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 None