BSD Guideline for the Use of Software with Research Health Information

Purpose
The purpose of this guideline is to assist faculty in ensuring that the software they wish to use to view, analyze or share Research Health Information (RHI) has been determined to provide an appropriate level of information security and data privacy for Research Health Information (RHI). RHI, while not HIPAA protected, is subject to state Privacy Laws. In addition, because RHI is the personal information of our patients, we are obligated to protect it at the same level as we would Personal Health Information (PHI).

Definitions
Research Health Information (RHI) - RHI is UChicago Medicine (UCM) patient data that is approved to be used for research by the BSD IRB.

Scope
This guideline is intended for Faculty, staff, students, and trainees who work with Research Health Information. The guideline outlines the steps to follow for approved use of a software to access, process, or share Research Health Information. The following exceptions apply:
- Software developed and accessed only by the research project team.
- Software developed by an entity (external to the research project team) that is implement on local infrastructure and accessed only by the research team.

Guidelines
This following step must be followed prior to employing software with Research Health Information.

Steps	Guideline	Description
1	IRB Approval	The approved IRB Protocol must include the name and version of the software and what it is being used to do.
2	Data Sharing	If the software is used to share data outside of University of Chicago, there must be an appropriate Data Use Agreement (DUA) or Data Transfer/Collaborator Agreement in place.
3	Information Security and Privacy Review	The software must have undergone assessment by the BSD Information Security Office (BSD ISO) and, as the result of that assessment, have been authorized for use with the IRB-approved protocol. The IRB number of the project and any supporting Data Use Agreements or contracts must be provided with the request for System Assessment and Authorization (SAA). The BSD ISO will engage the UChicago Privacy Office as needed during the SAA process. A step-by-step guide to obtaining an SAA of the software to be used can be found at: https://security.bsd.uchicago.edu/bsdsaa/.

Resources
[BSD Information Security Policies, Standards and Guidelines](#)
[Office of Clinical Research – HIPAA Privacy and Research](#)

Approval and Ownership

Responsible Offices: BSD Information Security Office and UC Privacy Office
Guideline Owners: BSD Chief Information Security Officer and UC Chief Privacy Officer

Version	Description	Revision Date	Review Date	Reviewer Name/Approver Name
1.0	Initial Version	08/15/2022		CCAS