

**COM DEPARTMENT:** Research  
**POLICY NUMBER:** RSCH-06-2019  
**REVIEW RESPONSIBILITY:** Senior Associate Dean for Research  
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**APPROVED:** \_\_\_\_\_

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**SUBJECT: REDCap Appropriate Use & Access**

### **Purpose**

This policy governs the appropriate access and use of REDCap (Research Electronic Data Capture) software housed at Florida State University College of Medicine for use by FSU faculty, staff, students, residents and their project colleagues.

### **Overview**

REDCap is a secure, web-based application that facilitates data collection for research and operational purposes. The software is 21 CRF Part 11 and FISMA/HIPAA compliant, and the data collected is stored on a secure server at the FSU College of Medicine. The added security of FSU CoM servers makes this software ideal to use for projects that include protected health information (PHI) or other sensitive information.

REDCap allows for role assignment by the administrator-approved project creator so that each member of the study team may have an assigned level of access. REDCap can also remove identifiers prior to exporting for analysis. An audit log records all project actions.

### **Policy**

All users of CoM REDCap software must abide by the guidelines set forth in this policy. Access for use of REDCap is managed and authorized by the FSU College of Medicine.

#### *IT Server Maintenance:*

CoM IT is responsible for the maintenance and operations of the software and servers that house the data collected through REDCap. The servers will be maintained in a HIPAA-compliant manner so that PHI gathered for projects may be properly stored.

#### *Software Access:*

CoM will appoint at least one REDCap administrator who is designated as a “super-user” in the REDCap system. This person will serve as the lead administrative contact for the College of Medicine. The primary function of the administrator is account creation for users per the request of the FSU-affiliated project lead or principal investigator (PI). Access for collaborators outside of FSU must be requested by FSU faculty or staff. In addition to REDCap account management, the FSU College of Medicine REDCap administrator has the right to:

- Report to the IRB, if requested, on the activity and authorized users of human subjects projects for monitoring protocol compliance, and
- Remove or disable user access for personnel as necessary and/or requested by the project lead or principal investigator.

#### Access Maintenance:

All CoM REDCap accounts will be verified annually by the CoM REDCap Administrator. Project Leads/Pis or their designated staff must verify which accounts remain active for the following year. If a member of the study team leaves their position or no longer requires access to CoM REDCap, the study PI or a member of the study team must notify the CoM REDCap Administrator to remove access.

#### Project Creation & Access:

Although CoM will assign an administrator to be responsible for the software, it is the responsibility of each individual investigator/lead or study team to create their project in the REDCap system. Video tutorials are available on the developer's website: [www.projectredcap.org](http://www.projectredcap.org). The CoM REDCap administrator may be of assistance to the study team when designing a project, but only for basic comments or questions.

The principal investigator, project lead or a designated member of the project team must complete the REDCap Project & Access Request form (Appendix A) in order to create a project and allow REDCap access for the study team. This form will document each user and their institutional affiliation and must be sent to the CoM REDCap Administrator.

Project-level access is controlled by the project creator who is an individual designated by the project PI/lead on the REDCap Project & Access Request form (Appendix A). Each project creator has the authority to add users to their project and designate each user's level of access. All users granted access to a human subjects research project must be listed on the IRB application and meet all human subjects and HIPAA training requirements.

#### Transition to Production Mode:

Initial project creation in REDCap is performed in development mode in which "test" data may be entered. To begin data collection, the project creator must request (within REDCap) that the project be moved to production mode. Proof of IRB approval must be presented to the CoM REDCap administrator for all human subjects research studies in order to authorize the change to production.

#### Study Archival

It is the project creator's responsibility to move the study into archival status once data collection and use are complete. This allows the project and the collected data to be stored securely.