

Service Level Agreement - REDCap
University of Alabama at Birmingham
Department of Medicine

Document Title:	DOM IT REDCap SLA
Document number:	DOM_IT_REDCap_01
Created on:	11-15-2018
Effective Date:	01-01-2019
Version:	7.0

Updated By	Date	Version	Remarks

Research Electronic Data Capture (REDCap) is a secure web-based data capture tools hosted by Department of Medicine (DOM) IT. Initially developed by Vanderbilt University, REDCap is now supported by a multi-institutional consortium. REDCap was built around HIPAA guidelines and withstood penetration tests performed by third-party security companies which resulted in worldwide adoption of REDCap as preferred tool for research data collection.

Department of Medicine (DOM) Information Technology (IT) has the largest implementation of REDCap instance at University of Alabama at Birmingham (UAB). REDCap is installed on a highly robust Linux environment in a physically secure datacenter. Data resides centrally on DOM-owned servers. Our REDCap infrastructure consists of a group of servers and tier-level security controls that integrate seamlessly. To protect data and to prevent unauthorized access, the entire system is collaboratively monitored by UAB Data Security and DOM IT. The web communication is encrypted via a commercial grade SSL certificate. The database is incrementally backed up throughout the day.

This agreement defines the terms and scope of services, as well as the responsibilities to be borne by project owners (Principal Investigator (PI)/ Project Coordinator). This agreement supersedes all previous agreements. Any modification to this agreement must be made in writing after consensus of both parties. Changes must also be included as an addendum. The following terms will apply:

SERVICES:

DOM IT offers two levels of services: Self-Service and Consulting. (Please see Appendix A)

SERVICE FEES:

Basic Package is included in the standard hosting fee whereas the consulting services are provided on demand. The full annual hosting fee is charged regardless of the project initiation date. (Please see Appendix B)

BILLING CYCLE:

Annual billing is generally done at the start of fiscal year (October). If payment is made with a grant account, arrangements can be made for retrospective quarterly billing. Consulting services are billed on a monthly basis.

Contact Information:

All inquiries and questions regarding REDCap can be directed to DOM REDCap Administrators at redcap@uab.edu

LIABILITY

Notwithstanding any other provision in this agreement to the contrary, IT support staff from the Department of Medicine, under no circumstances, shall be liable for the negligence or misconduct of project owners or persons under their supervision.

Notwithstanding any other provision in this agreement to the contrary, project owners or persons under their supervision, under no circumstances, shall be liable for the negligence or misconduct of Department of Medicine, or persons under their supervision.

In signing this agreement, the project owner agrees to the terms and conditions of the agreement.

SLA Date: _____

SLA#: _____

Project Title: _____

Project Type (Choose One from each below):

1. **Classic** _____ **Longitudinal** _____
2. **Survey only** _____ **Data Entry Only** _____ **Survey and Data Entry** _____
3. **Single site** _____ **Multi-site** _____

IRB Approval: If IRB approval is **not** required, initial here _____, otherwise complete:

Protocol #: _____ **(Please send an electronic copy to DOM IT)**

IRB Approval Date: _____ Project End Date: _____

Service Type (choose ONLY ONE. No OVERLAPPING/TRANSITION is allowed):

1. Basic _____ (The project owner's team will exclusively design and maintain the project)
2. Full/Consulting _____ **(Design/Setup exclusively by DOM IT)**

_____ I acknowledge the **consulting charges (Appendix A)** and the **Intellectual Property Rights (Appendix B)** for the project.

Billing Contact: Full Name: _____

Email: _____ **Phone:** _____

Account#: _____ **Account Type:** _____

Client:

Project Owner/ Principle Investigator (PI) Name: _____

Title: _____

Department: _____

Division/Center/Lab/Unit: _____

Signature (Client): _____ **Date:** _____

DOM- IT:

DOM-IT Authority-Name: _____

Title: _____

Signature (DOM-IT): _____ **Date:** _____

APPENDIX A – DESCRIPTION OF SERVICES

Project Administration

Even though the project owners and/or authorized users have flexibility during developmental phase, DOM IT REDCap Administrators have exclusive rights to the following tasks:

- Create new projects
- Approve and move all new projects (databases) into production
- Delete projects
- Other administrative task limited to super users

Response Time

The host servers and REDCap projects are expected to be operational and accessible 24x7. DOM IT will make every attempt to reduce unexpected system downtime. DOM IT will notify users for scheduled downtime and regular system maintenance.

Repurpose

In order to provide efficient service, project forms/instruments may be repurposed into other projects. When deemed appropriate, DOM IT will also submit certain forms to the REDCap Shared Library for possible consortium wide usage. (Please see Appendix B)

Service Types

A courtesy REDCap Overview session (1 hour- onetime) is available at no cost to every first-time investigator availing REDCap services with DOM IT.

All packages will include

- One (1) REDCap project hosting (**A grant or trial can have multiple REDCap projects.**)
- Data storage and backup

Basic - Self-Service

- Build Your Own Project: user flexibility to create and develop data collection instruments (forms), design fields, implement advanced features, etc.

Full – Consulting:

- DOM IT is responsible for design/setup/testing/ maintenance and updates
- Documentation for IRB submissions:
 - REDCap portion of the HSP Document
 - System Security Plan (SSP)
 - Risk Profile
 - Action Plan

Roles and Responsibilities

DOM IT Responsibility:

- **Infrastructure:** DOM IT is responsible for providing the necessary foundation for REDCap infrastructure including network architecture. DOM IT will apply patches from approved vendors and take appropriate measures to monitor and audit the servers and software.
- **REDCap Software:** DOM IT is responsible for maintaining the REDCap software and keeping it up-to-date. Dom IT is maintaining Standard latest version of REDCap to accommodate latest bug fixes and new features.

- **Security Best Practices:** DOM IT will adhere to rules enforced by UAB IT and HSIS for security best practices.
- **Risk Assessment:** DOM IT will annually review risk assessment of REDCap infrastructure.
- **Scheduled Maintenance:** DOM IT will have scheduled maintenance windows to install updates and to take preventive measures.
- **Backup and Data Recovery:** Backup will be done nightly, weekly, and monthly. Tape backups are kept at an off-site location. Depending on backup retention period, DOM IT will recover files that are accidentally deleted.
- **Inventory:** At the request of the customer, DOM IT will provide an annual inventory report of hosted projects.

Project Owner's responsibility:

- **IRB Approval:** REDCap projects that involve human subject research (per the U.S. Department of Health and Human Services [DHHS] Code of Federal Regulations definition) must have IRB approval before moving to production or commencing actual data collection. If the project is a multi-site study, the project owner attests that appropriate IRB and regulatory approvals have been obtained prior to data collection date. The project owners must submit all IRB approval/amendment documents before project initiation.
- **IRB Training:** All users (both UAB and External) must also successfully complete IRB Training. UAB users can refer to the following link for more information <http://www.uab.edu/research/administration/offices/IRB/Training/Pages/InitialIRBTraining.aspx>. External users should contact their IRB entity on training. It is project owner's responsibility to have proof of completion before allowing access.
- **Login Accounts:** Access to REDCap system is controlled and authorized for approved users only. UAB users must use their Blazer ID credentials to access projects. Non-UAB (external) users who are collaborating on the project must apply for local accounts through PI.
- **Data Privacy:** Project owners and coordinators agree to respect data privacy and will follow the principle of least privilege to assign minimum necessary access rights. Users who have full export rights must also have their computer systems encrypted.
- **Copyrighted Forms:** The investigators **must** obtain permission before reusing copyrighted forms (i.e. EORTC QLQ-C30, FACIT-SP-12) in REDCap. REDCap Shared Library forms are excluded.
- **Mandatory Yearly Audit:** PI or project owners must perform annual audit of their projects. (Please see **Appendix C**)
- **CITING REDCap:**
If you publish any work for which REDCap was used, you must cite in study manuscripts REDCap as the data collection and management. This is per our agreement with Vanderbilt (REDCap Owner).
Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr; 42(2):377-81.
Link to article: <http://www.sciencedirect.com/science/article/pii/S1532046408001226>
- **UAB IT Policies:** It is customer's responsibility to adhere to IT policies outlined by UAB, DOM, and their own department.

APPENDIX B – SERVICE FEES

The following are service fees charged by DOM IT. DOM IT reserves the right to change fees.

Project Fee

1. Non-Research Specific Survey ONLY Projects (no Data Entry option): **FREE**
Examples: Non-IRB Regulated Operational, Process Improvement, Basic/Anonymous surveys. SINGLE Survey only. Anytime, a project used for any data entry will be considered for annual fee.
2. All other Research/Operation/Quality Improvement Data Entry/Survey Projects. Any kind of project (e.g., Classic, Longitudinal, Single-Site, Multi-Site, With or Without Surveys): **\$500 per project, per year**

Consulting Services

DOM IT is equipped with professional staff to help with design/setup/training custom solutions. Consulting services are optional and can be requested at any time during the course of the project. Consulting fee is **\$75/hour, billable to 15 minutes increments**.

Intellectual Property

For **full** consulting type projects, DOM IT retains exclusive rights to the design and implementation tasks of the REDCap project. **DOM IT also holds the intellectual property (IP) rights for such projects. Projects including source code, data dictionary, design framework, etc. may not be transferred or repurposed to third-party/external systems without explicit approval from DOM IT.** However, exceptions are allowed for extraordinary situations but only after reaching a mutual agreement between DOM IT and project owner.

After obtaining approval from DOM IT, the investigator may transfer projects to another system. However, DOM IT will no longer be responsible for both technical and operational for such transferred projects. The investigator assumes that it is his/her and the third-party system administrators' responsibility to make project operational.

Admin Tax

If the invoice is paid on non-UAB account, 5% admin tax will be levied on the total amount. Examples of Non-UAB accounts are HSF accounting units, external (non-UAB) checks.

Payment with a Grant Account

Invoices paid with a Grant account must be processed using a Cost Transfer Form, which can be obtained from UAB Financial Affairs office or website.

APPENDIX C – MANDATORY YEARLY Project Audit (Performed by PI/ Project Owner)

The projects must be audited on an annual basis to reduce the likelihood of noncompliance and also to follow security best practices. Please provide a copy of annual audit performed to DOM IT before end of fiscal year.

The Principal Investigator (PI) or the project coordinator must perform the following tasks on each REDCap project:

1. **IRB Approval Documentation:** The PI or the project owner must show proof of IRB approval for studies dealing with human subjects. DOM REDCap Administrators must receive the initial IRB Approval Form (Form 4) and the successive IRB Project Revision/Amendment Forms.
2. **IRB Training:** Make sure that all users are up-to-date on IRB Training.
3. **User Rights:** Project owners should periodically review user access rights and disable access for users on the project who are no longer part of the study or project. If DOM IT managing project for you, please inform formally to change status of such users.
4. **User Matrix:** Make sure the User Matrix Excel file is up-to-date and enforced. Project owners should work on the principle of “least privilege”.
5. **Hard Disk Encryption:** Make sure that all computers (both desktops and laptops) used by “full-export-rights users” are whole-disk encrypted using either File Vault (for Macs) or BitLocker (for Microsoft Windows). Please see UAB’s official encryption guidelines: <https://www.uab.edu/it/home/encryption-guidelines>
6. **Project Validity:** Project owners should identify the validity of the project to maintain status as per protocol. In case of any changes other than continuing as active, project owners should inform DOM IT formally to change the project status appropriately aligned with study/ grant/ protocol requirements.