

Service Level Agreement (REDCap)

Department of Medicine
University of Alabama at Birmingham

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Nazmul Islam	2014-05-01	1.0	
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Nazmul Islam	2021-02-01	8.1	Added custom programming

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

DOM IT utilizes Priority Software's FBS system and follows fiscal year. Billing is generally done annually and invoices are sent around October. Consulting invoices, however, are done quarterly.

CONTACT

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:** _____

INVESTIGATOR:

Project Owner/ Principle Investigator (PI) Name: _____

Title: _____

Department: _____

Division/Center/Lab/Unit: _____

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

DOM IT:

Name: _____

Title: _____

Signature: _____ **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
- User Rights for both system and project levels
- Other administrative task limited to super users

SYSTEM UPTIME

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

RESPONSE TIME

DOM IT is a professional service provider and values customer service as the paramount service trait. While a specific response time cannot be guaranteed, DOM IT pledged to be courteous, prompt, and switch in responding to service calls.

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 first-time investigators.

All packages 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. PI or faculty research team carries out design and testing of his/her research database.

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 Mitigation:** For a trustworthy service operator, DOM IT will assess and mitigate any risks identified by any party (DOM IT, UAB IT or HSIS).
- **User Rights:** REDCap employs tiered access for enhanced security. Users must be whitelisted at system level first and then added to specific projects. DOM IT will retain sole rights for both these user rights assignments and will apply based on PI's direction and IRB protocol.
- **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. Email DOM IT (redcap@uab.edu) copy of your IRB approval letters.
- **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 <https://www.uab.edu/research/home/irb-training-page>. External users should contact their institutional IRB. It is project owner's responsibility to have and send DOM IT proof of completion. Without proof of IRB training, access to REDCap may not be granted.
- **User Rights and 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. Collaborating Non-UAB (external) users must apply for local (table-based) accounts through PI. It's also PI or (project owner's) responsibility to let DOM IT know during staff turnover.
- **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). 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 tool. This is per our agreement with Vanderbilt (REDCap Owner). We recommend the following boilerplate language”

Study data were collected and managed using REDCap electronic data capture tools hosted at UAB Department of Medicine IT (DOM IT).^{1,2} REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

¹PA Harris, R Taylor, R Thielke, J Payne, N Gonzalez, JG. 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.

²PA Harris, R Taylor, BL Minor, V Elliott, M Fernandez, L O’Neal, L McLeod, G Delacqua, F Delacqua, J Kirby, SN Duda, REDCap Consortium, **The REDCap consortium: Building an international community of software partners**, *J Biomed Inform.* 2019 May 9 [doi: 10.1016/j.jbi.2019.103208]

Link to articles:

<http://www.sciencedirect.com/science/article/pii/S1532046408001226>

<https://www.sciencedirect.com/science/article/pii/S1532046419301261>

- **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. **The cost structure is subject to change.**

PROJECT FEE

1. Non-Research Specific Survey ONLY Projects (no Data Entry option): **FREE**
Examples: Non-IRB Regulated Operational, Process Improvement, Basic/Anonymous SINGLE surveys ONLY (no back-end data entry).
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.

Standard (UI) Consulting fee is **\$75/hour, billable to 15 minutes increments.**

Advanced (Custom Programming) Consulting fee is **\$150/hour, billed hourly.**

Analytics Core (data scientist tasks, Tableau dashboard, etc.) fee is **\$150/hour, billed hourly.**

TRAINING

Individual and/or group training on advanced REDCap topics are billed at \$75/hour/presenter plus \$50 per attendee. The purpose of training is to explore some of the advanced features of REDCap, it's **not** intended to replace the consulting services that DOM IT provides.

For an example, if two (2) DOM IT staff/presenters provide three (3) hour training to a group of five (5) participants, the total cost for that particular training will be \$700.00 (2x3x\$75 + 5x\$50).

INTELLECTUAL PROPERTY

DOM IT retains exclusive rights to the design and implementation tasks of the REDCap projects designed by its staff. **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. **Contact DOM IT for an estimate.**

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.

OPTIONAL SERVICES

As a professional REDCap service provider, we also offer these optional services that enhances your REDCap experience. These are generally upfront/first year **per project** costs.

eConsent Module: \$1,000.00

REDCap Mobile App or MyCap App: \$500.00

Twilio IVR (voice prompted response): \$500.00 + Twilio subscription and call costs (PI provided Twilio account can be used)

DOM IT also provides data visualization and analytical service.

Tableau Dashboard: \$2,000/dashboard/year + Tableau License Fee (annual, varies by type)

Where applicable, if your funding/regulatory agency has additional requirements, these additional charges will apply.

Test (Development) Database: \$500/database/year

Dedicated REDCap Production Server (Single, Consolidated): \$5,000 (annual)

Dedicated REDCap Production Server (Distributed – 3 role based servers): \$15,000 (annual)

Dedicated REDCap Testbed Server (Single): \$5,000 (annual)

Dedicated REDCap Redundant Testbed Server (Single): \$2,500 (annual)

Validation by External Auditor (estimated one-time, payable to auditor): \$12,000.00*

Compliance Documentations/Annual Deliverables (estimated): \$2,500.00*

**multi-site validation/documentation may be higher.*

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.

INVOICING

DOM IT has adopted Priority Software's FBS system for streamlined billing. Initial invoice will be sent at project initiation. Annual invoices will be sent in October and consulting invoices will be sent quarterly. Invoices will be sent to a named individual for review, the duration of which will be at least 14 days. If no discrepancy, the UAB GL/GA accounts will be charged automatically. HSF accounts and invoices will be handled manually.

ACCOUNT NUMBER

DOM IT will invoice this Oracle account number for all applicable charges: **<account number>**.

APPENDIX C – MANDATORY YEARLY Project Audit (To Be 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.

APPENDIX D – DOM IT CONTACT

TECHNICAL QUESTIONS

For technical questions and faster service, contact **DOM IT REDCap team** at redcap@uab.edu. Your request will automatically be logged and visible to the entire team.

Joy Bhadhan Roy, *Programmer/Analyst*

E-mail: joyroy@uab.edu

Phone: 205-934-2804

BILLING QUESTIONS

For billing related questions, contact:

Nazmul Islam, *Director of IT*

E-mail: nislam@uab.edu

Phone: 205-934-3616

Joy Bhadhan Roy, *Programmer/Analyst*

E-mail: joyroy@uab.edu

Phone: 205-934-2804

DOM IT GENERAL

Location: Boshell Diabetes Building, BDB-479/824

E-mail: domhelp@uab.edu

Phone: 205-975-4357 (975-HELP)

Website: <http://www.uab.edu/domit>

HelpDesk (Kayako): <https://support.dom.uab.edu> (*BlazerID protected*)