

Service Level Agreement - REDCap

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. As a result, it has been adopted as a data management and survey tool by reputable universities worldwide.

DOM IT has the largest implementation of REDCap instance at 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. Furthermore, the REDCap website is accessible within the UAB network only, and remote users must use UAB VPN. The database is incrementally backed up throughout the day and a nightly backup is also performed.

This agreement defines the terms and scope of services, as well as the responsibilities to be borne by project owners. 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 Basic Package and Consulting. Description of services is outlined in **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. Services Fees are discussed in detailed in **Appendix B**.

BILLING

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.

CONSULTING SERVICES

DOM IT is equipped with resources to design and build project for you. Consulting services are optional and can be requested at any time during the course of the project. Refer to **Appendix A** for description of such services and **Appendix B** for our rates.

TRAINING

In addition to the initial overview courtesy session, DOM IT can provide one-to-one or group training sessions on advanced topics of REDCap. Refer to **Appendix B** for our rates on training.

GRANT LANGUAGE

The following boilerplate language can be used on documents submitted to IRB.

Study data will be collected and managed using REDCap electronic data capture tool. REDCap (Research Electronic Data Capture [1,2]) is a secure, Web-based application designed to support data capture for research studies, providing: (1) an intuitive interface for validated data entry; (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 importing data from external sources. There are procedures for Double-Data-Entry, and user rights may be assigned on a form-by-form basis within each study, allowing blinding of study personnel to certain information. For multi-center studies, Data Access Groups may be set up to allow users access only to their site's data. For quality control purposes, REDCap offers real-time range checking during data entry. There are also data visualization tools to assist in data cleaning and evaluation. The Data Export Tool includes methods for data de-identification and exports some or all data to Excel, SAS, SPSS, R, S-Plus, and Stata. REDCap has been disseminated for use locally at other institutions and currently supports 1647 academic/non-profit consortium partners in 94 countries and over 284,000 end-users.

The REDCap database is hosted at the UAB Department of Medicine's (DOM) secure data center, which will be used as a central location for data storage, processing, and management. DOM REDCap servers reside in a secure VMWare virtualized environment and behind an enterprise grade Palo Alto firewall. DOM also maintains an active Disaster Recovery Site where data are replicated to using a private VLAN. The REDCap website is available to campus network only and UAB VPN connection is required for remote users. All web communications are protected via SSL encryption. Only IRB approved research team members will have access to the REDCap. Access is granted according to "the principle of least privilege." Each team member will be granted access to the REDCap data system through a secure login.

[1] P.A. Harris, R. Thielke, R. Taylor, J. Payne, N. Gonzalez, J.G. Conde. Research Electronic Data Capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics*, 2008.

[2] <http://www.project-redcap.org>

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).

Study data were collected and managed using REDCap electronic data capture tools hosted at UAB Department of Medicine.¹ REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 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 importing data from external sources.

¹Paul 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>

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.

Date: _____

Grant Name: _____

Project Name: _____

Project Coordinator: _____

Project Owner (PI): _____

Department: _____

Project Type (Choose One from below and specify sub-category):

1) Survey Only. 1a) Single Survey _____, or, 1b) Multiple surveys _____

2) Data Entry. 2a) Single-site _____, or, 2b) Multi-site _____

3) Data Entry with Surveys: _____

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

Protocol #: _____ **(Please send a copy of IRB Protocol and approval)**

IRB Approval Date: _____ Project End Date: _____

Service Type (choose One. No OVERLAPPING is allowed):

Basic _____ (The project owner's team will exclusively design and maintain the project)

Consulting _____ **(Design tasks will be done exclusively by DOM IT. Initial next line)**

_____ I acknowledge the additional **charges (Appendix A)** and the **Intellectual Property (Appendix B)** rights for consulting projects.

Grant Account: If invoices will be paid with Grant accounts, please check here _____.

NOTE: Refer to and fill out **Appendix D** if multiple projects are being included under this SLA.

Rev. 6.5

Project Coordinator: _____

Principal Investigator: _____

Approved By: _____

Nazmul Islam
Director of IT
Information Systems Security Officer (HIPAA ESC),
UAB Department of Medicine

APPENDIX A – DESCRIPTION OF SERVICES

Project Life

The project will be hosted and actively maintained per the timeframe specified in the approved IRB protocol. Extension will be granted by signing an amendment. At the completion of the study, the REDCap project will either be archived or deleted (along with the underlying data) per IRB and HIPAA protocols.

Project Status

Even though the project owners and/or authorized users have tremendous 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
- Approve and implement any changes to a production database
- Archive projects
- Delete projects

Response Time

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

Repurpose

In order to provide efficient service, project forms/instruments can be repurposed in the future. When deemed appropriate, DOM IT will also submit certain forms to REDCap Shared Library for possible consortium wide usage.

Service Types

There are two distinct levels of services for REDCap project hosting. While the Basic Package is included in the annual hosting fee, consulting services are provided on demand.

Basic Package - Self-Service

- REDCap overview session (2 Hours max for **first time investigators ONLY**)
- One (1) REDCap project hosting (**A grant/trial can have multiple REDCap projects**)
- Build Your Own Project: user flexibility to create and develop data collection instruments (forms), design fields, implement advanced features, etc.
- Unlimited number of forms and fields per project
- Data storage and backup
- Extensive collection of REDCap resources
- Basic support (email and phone) such as adding user, assigning user roles, cross-checking and audit before moving to production, simple reports, best practice suggestions, and quick solutions. DOM REDCap Administrators can be reached at redcap@uab.edu.

Full Package - Consulting (On Demand)

- All components of Self-Service Basic Package
- Documentation for IRB submissions:
 - REDCap portion of the HSP Document
 - System Security Plan (SSP)
 - Risk Profile
 - Action Plan

- Training on advanced features (billed hourly and per person). The training is meant to touch the advanced features of REDCap. It is not intended to replace the other consulting services.
- Project planning, form design, and creation. Under consulting service, DOM IT will solely be responsible for assessing, brainstorming, designing, building, validating, and testing the project.
- Project migration from non-DOM REDCap instance to DOM REDCap instance
- Configuration of advanced features such as Branching Logic, Data Access Group, Field validation, Data Dictionary creation, multiple project linking, data mapping, etc.
- Data manager related tasks such as data consolidation, import, export, and extraction.
- Report building, data analysis, etc.
- DOM IT holds the intellectual property rights for projects developed under this agreement.

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. All project related data will be housed in a secure DOM-owned datacenter. DOM IT will act as the first contact for all REDCap project related inquiries.
- **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. Monthly 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 BlazerID credentials to access projects. Non-UAB (external) users who are collaborating on the project must apply for XIAS accounts (<http://www.dpo.uab.edu/xias>). PI is responsible for maintaining access rights to project.
- **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.
- **Yearly Audit:** PI or project coordinators must perform annual audit of their projects. **Annual audit of project is a mandatory task.** Refer to **Appendix C** for more information.
- **Publications:** Any publication resulting from the use of REDCap as a data collection tool should be properly cited.
- **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.

Basic Package - Hosting Fee (Annual)

The REDCap projects are charged annually irrespective of the project creation date. Tiered fee structure has been implemented based on the efforts involved for different category of projects.

Survey ONLY Projects:

- **Basic Survey (no Data Entry option):** \$200 per survey. Duration is two (2) months

Data Entry Projects (Annual):

- No Surveys
- **Single-site (UAB) Projects:** \$500 per project
- **Multi-site (UAB and External Collaborators) Projects:** \$750 per project

Data Entry + Survey Projects (Annual):

- **Single-site (UAB) Projects:** \$1,000 per project
- **Multi-site (UAB and External Collaborators) Projects:** \$1,500 per project

Other Projects (Annual):

- **Archived Projects:** \$200 per project
- **Inactive Projects:** \$200 per project

Full Package - Consulting Services

DOM IT is equipped with professional staff to help you with advanced features of REDCap. Our consulting rate is **\$75/hour, billable to 30 minute increments. The actual cost of a consulting project, however, will be dependent on the final and cumulative number of forms, fields, and the complexity of the database.** Billing for such services is done on a monthly basis, but other mutually agreed upon arrangements can be implemented. Project owner will get detailed work list along with the invoice.

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.

Training

Individual and/or group training on advanced REDCap topics are billed at \$75/hour plus \$50 per attendee. For an example, if we provide two (2) hour training to a group of five (5) participants, the total training cost will be \$400.00 (2x\$75 + 5x\$50).

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.

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.

Contact Information

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

APPENDIX C – YEARLY PROJECT AUDIT (BY PI)

The projects must be audited on an annual basis to reduce the likelihood of noncompliance and also to follow security best practices. The Principal Investigator (PI) or the project coordinator must perform the following tasks on each REDCap project:

1. **Mandatory Annual Audit:** Annual audit of projects by project owner is a mandatory task.
2. **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.
3. **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”.
4. **User Rights:** Project owners should periodically review user access rights, and disable access to users who are no longer part of the study or project.
5. **Hard Disk Encryption:** Make sure that all computers (both desktops and laptops) used by “full export right users” are encrypted with approved application (i.e. PGP, FileVault, BitLocker)
6. **Data Dictionary:** Keep a hard copy of each revision of data dictionary.
7. **Check Mate:** Run Check Mate against data dictionary to check for identifiers. DOM REDCap Administrators can assist you in making this tool available to you.
8. **IRB Training:** Make sure that all users are up-to-date on IRB Training.

APPENDIX D – OTHER PROJECTS BY THE SAME PI

In order to reduce contractual signing efforts and increase efficiency, please list the **project titles and IRB protocol numbers** owned by the same PI as they appear on REDCap. Also, include the type of services (Basic vs Consulting) you opted for. The following REDCap projects, owned by the same PI, will be covered under the terms and conditions outlined in the previous pages.

- 1. _____
- 2. _____
- 3. _____
- 4. _____
- 5. _____
- 6. _____
- 7. _____
- 8. _____
- 9. _____
- 10. _____