UConn Health REDCap User Agreement

Effective as of August 8, 2019

1. INTRODUCTION

Thank you for choosing REDCap (Research Electronic Data Capture) hosted by UConn Health’s Research IT (RIT) and the Clinical Research Center (CRC). REDCap is a secure, web-based software platform designed to support data collection strategies for research studies. The REDCap project was initiated at Vanderbilt University and is now composed of a consortium of over 3600 active institutional partners from over 130 countries.

Please read this User Agreement (UA) carefully before using UConn Health REDCap Services. This UA contains the terms and conditions under which RIT and CRC provide their REDCap Services to you and describes important information on how the services should be accessed and proper use. Its use is subject to the terms and conditions set forth in this UA, as well as all federal, state, local and other applicable law; all University of Connecticut and UConn Health rules and policies; and all applicable terms in the REDCap License Terms.

2. YOUR AGREEMENT TO THE TERMS

By clicking “I ACCEPT” or otherwise accessing or using any of the UConn Health REDCap Services, you acknowledge that you have read, understand, and agreed to be bound by the terms. If you do not agree with (or cannot comply with) the User Agreement, then you may not use the UConn Health REDCap Services or access any content.

3. CONDITIONS OF USE

UConn Health REDCap is permitted for non-commercial research purposes only and may not be used by for-profit entities, for-profit work or the conduct of clinical care. Forms or surveys unrelated to research may be administered using an alternate service. (e.g. Qualtrics provided by UConn Storrs, SurveyMonkey, etc.)

If collecting Personal Identifiable Information (PII) or Protected Health Information (PHI), all members of the research project team, including Principal Investigators (PIs), designated Project Administrators (PAs), and other project members should complete the CITI Basic Course Requirement, before utilizing REDCap.

4. ELIGIBILITY

UConn Health REDCap is available to all University of Connecticut and UConn Health faculty, staff, and currently enrolled students for research related purposes. We also allow affiliate users who are working in collaboration with a Private Investigator (PI) from UConn or UConn Health and have reciprocal IRB agreements with UConn Health IRB.

5. OBTAINING A REDCap ACCOUNT

A REDCap account may be obtained by submitting a completed online REDCap Account Request Form (attainable only by contacting the REDCap administrator at redcap@uchc.edu). An account will be created for both the Development (test/sandbox) and Production system environments. No generic (multi-user) accounts can be granted.

6. USER ACCOUNT RESPONSIBILITY

Users may not share their login credentials with other study personnel working on the project as this would be a breach of confidentiality and is grounds for disciplinary action. You are responsible for maintaining the confidentiality of your password and account. Users agree to immediately notify UConn Health REDCap Administrator of any unauthorized use of your password or account or any other breach of security.
7. Requirements

All project team members who will access and work in the UConn Health REDCap system must complete the Introductory Overviews and Basic Features & Functionality REDCap video training modules (approx. 1 hour) prior to using REDCap. PIs or designated PAs who are accessing and working in UConn Health REDCap must also complete the Project Types module (approx. 20 min). These are the minimum requirements for training. All users are encouraged to view additional REDCap training videos as needed.

If the project for which UConn Health REDCap will be used involves human subjects research (per the U.S. Department of Health and Human Services [DHHS] Code of Federal Regulations definition), it must have Institutional Review Board (IRB) approval before the project can be moved to production for data collection. Additionally, the PI or designated PA must provide the UConn Health REDCap administrator with the approved IRB documentation attached to the online Project Deployment to Production Form before moving the project to production. Collect only the minimum necessary PII/PHI and separate PII/PHI from study data and responses (de-identify). Recommended reading before collecting Protected Health Information (PHI): A beginner’s guide to avoiding Protected Health Information (PHI) issues in clinical research – With how-to’s in REDCap Data Management Software

8. Roles & Responsibilities

Complying with HIPAA’s requirements is a shared responsibility. Users sharing and storing PHI in REDCap are responsible for complying with HIPAA safeguards, including:

- Using and disclosing only the minimum necessary PHI for the intended purpose.
- Ensuring that PHI is seen only by those who are authorized to see it.
- Obtaining all necessary authorizations, data-sharing agreements and Business Associate Agreements for using and disclosing PHI.
- Following any additional steps required by your unit to comply with HIPAA, IRB and UConn Health Policies and Procedures.

The PI or designated Project Administrator (PA) oversee the proper handling and compliance of the project set-up, data collection and allocation of user rights in the project as the relevant compliance unit approved it and that any changes made to the protocol must be approved by the relevant compliance unit. Compliance-related activities include, but are not limited to, utilizing approved surveys, granting access to approved research team members with appropriate privileges, and exporting data as de-identified.

Users agree NOT to use or store any of the following sensitive data in the UConn Health REDCap system:

- Account numbers
- Social Security number
- Medical Record number
- Mother’s Maiden names
- Health Plan number
- Certificate/license numbers
- IP address
- Financial/PCI data
- Vehicle identifiers
- Biometric ID
- Full face/identifying photo
- Audio & Video Files

(Continued on next page)
8. Roles & Responsibilities (continued)

- HIPAA data not approved by the IRB protocol.
- Data related to International Traffic in Arms Regulations (ITAR). ITAR control the export and import of defense-related articles and services on the United States Munitions List (USML).
- Any other sensitive data sanctioned by federal, state, regional, and university regulations.

The user understands that any fields containing personally identifiable or health information must be marked as identifiable in the REDCap project and data containing PHI/PII should be de-identified prior to download and only downloaded to secure & encrypted computers that are approved by UConn, UConn Health or your local institution.

9. Proper Use of the REDCap System

The UConn Health REDCap system consists of two separate environments, Development (test/sandbox) and Production. The Development (test/sandbox) system is strictly used for design, development, testing, and training with simulated mock data. The Production system is used for live “real” data collection. These environments must be used as intended and live data collection and/or storage of "real" data is strictly prohibited in the Development system. Development system data will not be migrated to Production and will be deleted when your project is moved to Production.

REDCap users are allowed to only create a new project in the Development system. Projects titles in Development should be labeled with the prefix 'Dev-'. To migrate projects from the Development to the Production system the requester must click the ‘Move Project to Production’ button at the bottom of the Project Setup page. Once the REDCap administrator receives the request, a link to the online Project Deployment to Production Form will be sent to the requester. The requester will submit that form with any required information and IRB documentation to the REDCap administrator for approval. Please allow 1-5 business days for the move request to be approved and moved to Production.

Once a project is moved to Production, any further changes will need to be approved by the REDCap administrator before taking effect. Edits in Production will be permitted for minor/simple fixes, such as typos. Making major changes to a project that is in Production should only be done as a last resort. Major changes must be done in Development, retested, and then updated in the Production system. Altering a project that is in Production and has data can cause data loss in some instances. If anything is questionable, you will receive an email from the administrator to confirm that you want to commit to the changes. The requester should be aware that changes to any variables might affect programmed calculations and/or branching logic. It is the responsibility of the requester to review and test all calculated fields and branching logic prior to submitting changes. The impact to these fields will NOT be tested by the REDCap administrator. Please allow 1-3 business days for your draft changes to be reviewed by a REDCap administrator.

REDCap is NOT to be used as a long-term storage or data repository beyond the active life of the project or study. The PI or a designated PA is responsible for exporting the collected data from their project to another long-term secure storage solution once data collection is complete. The PI or PA must ensure adherence to UConn Health Data Storage and Security Policies and File Requirements & Record Retention Requirements of the IRB, study sponsor, and federal agencies with oversight of the project. Once data has been exported and saved the PI or PA must archive the project by utilizing the archive feature under the ‘Other Functionality’ tab of the project. The archived projects and its data will be deleted from the Development and Production systems after 3 months from study completion date.
10. FEES AND PAYMENTS FOR SUPPORT

The PI or a designated Project Administrator (PA) agrees to the Support Fee Schedule as described in Appendix A – Support Fee Schedule.

There are no fees for using the Development (test/sandbox) system.

Support fees will be invoiced at the time of moving the project to production and billed on a yearly basis from the original invoice date.

Payment is due within 90 days from invoice date.

Fees are waived for current UConn students that do not have a grant-funded study.

UConn Health Clinical Research Center reviews the fees on a yearly basis and may change the fees at any time, provided that, for support services billed on a yearly basis, the change will become effective only at the end of the then-current billing cycle of your project. UConn Health REDCap support service will provide you with advance notice of any changes in fees.

11. REDCAP MOBILE APP

The Principal Investigator or their designated Project Administrator must request authorization from UConn Health REDCap system administration to use the REDCap Mobile App for each REDCap project.

To request the use of the REDCap Mobile App, please submit an email to the REDCap administrator (redcap@uchc.edu) for a “Mobile App Project Review” request.

A consultation with the UConn Health REDCap administrator will be scheduled to review the suitability of the Mobile App for your project and to review the REDCap Mobile App Terms of Use Agreement, additional security procedures and precautions that are required with the use of the Mobile App.

12. AUDITING

All activities made by users on a REDCap project are logged and viewable by REDCap administrators and users that have been granted ‘Logging’ in ‘User Rights’ located in the Applications section in your REDCap dashboard. The user ID, time stamp and survey activities that may contain PHI/PII are logged with the activity details. The use of the UConn Health REDCap system establishes user’s consent to all monitoring and logging of their activities.

Monthly audits will be conducted on the Development system to make sure that no real data is being captured. We will periodically delete data and projects from the Development and Production systems if they are no longer in use. We will notify users via email prior to the deletion of projects.

13. CHANGES TO THE AGREEMENT

UConn Health Research IT (RIT) & The Clinical Research Center (CRC) may revise the User Agreement (UA) from time to time, and reserves the right to do so in its discretion. Typically, these changes are made to conform to current practices, comply with changing regulatory requirements, or other similar purposes. If UCH RIT and CRC modifies this UA in a manner that materially changes the terms or scope of the REDCap Services made available to you, we will make reasonable efforts to post a prominent notice on the UConn Health CRC REDCap website and notify those of you with a current REDCap account via email. Your continued use of the UConn Health REDCap Service after reasonable notice of such changes to the UA has been provided will constitute your consent to the revised UA terms. If you have any questions about this UA, please contact us at: redcap@uchc.edu.
14. Citing REDCap

It is a condition of UConn Health licensing for REDCap that researchers reference REDCap in their publications. Please cite the publications below in study manuscripts using REDCap for data collection and management. We recommend the following boilerplate language:

Study data were collected and managed using REDCap electronic data capture tools hosted at UConn Health. 

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.


Link to articles: http://www.sciencedirect.com/science/article/pii/S1532046408001226

(Appendix A – Support Fee Schedule on next page)
## APPENDIX A – SUPPORT FEE SCHEDULE

<table>
<thead>
<tr>
<th>2 REDCap projects per IRB study or non-IRB study at one institution</th>
<th>What is included</th>
<th>Support Fee</th>
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<tbody>
<tr>
<td>• Creation of new user accounts for the organizing institution.</td>
<td></td>
<td>$75/yr. per study</td>
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<tr>
<td>• 1 hour of initial consultation.</td>
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<td>• Resetting passwords</td>
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<td>• REDCap online training resources</td>
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<tr>
<td>• Quality review when your project is submitted for production.</td>
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<tr>
<td>• Moving your project to production.</td>
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<tr>
<td>• Email support for questions, requests and basic troubleshooting of problems.</td>
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<tr>
<td>• Reviewing and approving changes for projects already in production.</td>
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<tr>
<th>3 or more REDCap projects or REDCap projects that have multiple outside institutions/vendors (outside of UConn or CCMC) with multiple users.</th>
<th>What is included</th>
<th>Additional one-time fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Moving 3 or more REDCap Projects to production</td>
<td></td>
<td>$75 fee</td>
</tr>
<tr>
<td>• Creation of new user accounts for multiple institutions/vendors</td>
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</table>

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<tr>
<th>Hourly Services</th>
<th>What is included</th>
<th>Support Fee</th>
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</thead>
<tbody>
<tr>
<td>• Configuration of secure access of multiple users in a project.</td>
<td></td>
<td>$75/hr.</td>
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<tr>
<td>• Development support and assistance building REDCap projects.</td>
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<tr>
<td>• Support and assistance with complex configurations, branching logic or calculations.</td>
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<tr>
<td>• Twilio survey configuration</td>
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<tr>
<td>• Customized reports</td>
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<tr>
<td>• Data extractions and conversions</td>
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<tr>
<td>• One-on-one training</td>
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