UCH REDCap User Agreement

Effective as of February 1, 2023

1. INTRODUCTION

Thank you for choosing REDCap (Research Electronic Data Capture) hosted by UConn Health's Clinical Research Center (CRC) and Academic IT Services (AITS). 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 UCH REDCap User Agreement (UA) carefully before using UCH REDCap Services. This UA contains the terms and conditions under which the CRC and AITS provide their REDCap Services to you and describes important information on how these services should be accessed and the proper use. Its use is subject to the terms and conditions outlined in this UA, as well as all federal, state, local, and other applicable laws; all UConn Health and University of Connecticut rules and policies; and all applicable terms in the REDCap License Terms.

2. ELIGIBILITY

Usage Eligibility
REDCap usage is limited to non-commercial **research purposes only**, as defined by DHHS. Federal regulations define research as the systematic investigation, including development, testing, and/or evaluation, designed to develop or contribute to generalizable knowledge. For more information, please see Appendix A (research determination).

REDCap may not be used by for-profit entities, for-profit work, or the conduct of clinical care. Nor can it be used as a registry and/or repository. Forms, questionnaires, or surveys related to commercial research (including industry-sponsored clinical trials) or unrelated to research may be administered using an alternate service: Survey Tools & Assessment.

User Eligibility
REDCap accounts are available to all University of Connecticut and UConn Health faculty, staff, and currently enrolled students for research-related purposes. External Collaborator accounts will only be given to users via sponsorship by their UCH/UConn Principal Investigator (PI). External users will not have the ability to create new projects; they can only access projects to which they are formally added.

All REDCap users must complete the Introductory Overviews, Basic Features & Functionality, and Project Types video training modules (approx. 1 hour) before using REDCap. These are the minimum training requirements. All users are encouraged to review additional REDCap training materials as needed (see Section 7).

Project Eligibility
All projects must involve a PI who is a faculty member, employed and paid, by UConn Health or UConn. All projects must show proof of research use by providing the appropriate IRB documentation (see Figure 1):

- a UConn/UCHC approval letter or exempt determination letter, or
- a letter from the UConn/UCHC IRB agreeing to rely on another IRB for oversight, or
- a Human Subjects Research Determination form signed by the UConn/UCHC Human Subjects Protections Office indicating that the project is "NOT human subjects research" - *the project MUST still be for research purposes only as defined by DHHS*

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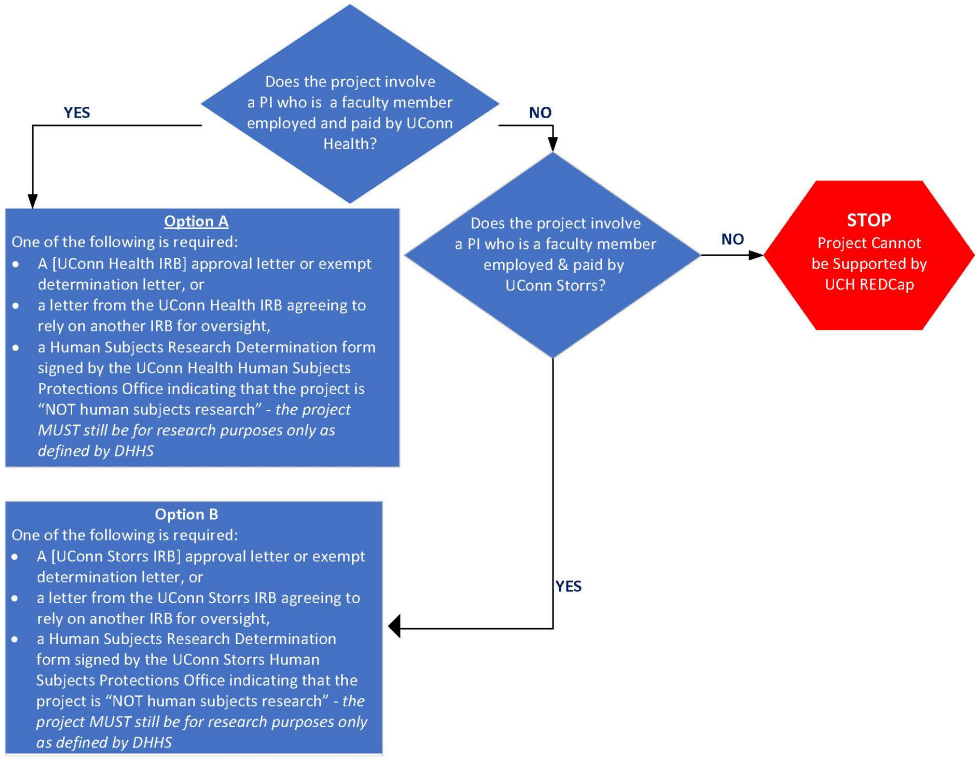
The approved IRB documentation must be provided to the REDCap administrator along with the online Move to Production request form. The PI information listed on the request form must match the approved IRB documentation. See Section 4 for additional PI responsibilities.

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

Figure 1.
Project Eligibility Requirements



3. OBTAINING A REDCAP ACCOUNT

Access to the REDCap system is controlled and authorized for approved users only. A REDCap account may be obtained by submitting a completed online REDCap Account Request Form. An institutional email address is required – no personal email addresses (Gmail, Hotmail, etc.) are acceptable. No generic (multi-user) accounts can be granted.

Separate accounts will be created for both the Development *(test/sandbox)* and Production system environments.

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4. PI RESPONSIBILITIES

The PI is ultimately responsible for the REDCap project and its associated users. The PI is responsible for personally conducting or supervising the conduct of human subject research and for protecting the rights, safety, and welfare of the subjects enrolled in the research. PIs are expected to ensure research is conducted in an ethical manner and in accordance with all federal, state, and local laws and regulations, and institutional policies, requirements, or determinations of the IRB, and in accordance with this agreement.

All PIs must maintain an active REDCap user account and be listed on the associated project. It is the responsibility of the PI, or their designated project manager, to authorize study staff access to their project in REDCap, assign user rights and privilege access, and/or remove users from their project who are no longer associated with the study. The PI must let the REDCap Administrator know if users need to be removed from the REDCap system.

The PI is responsible for exporting the collected data from their project to another long-term secure storage solution once data collection is complete. The PI 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.

5. CONFIDENTIALITY AND PRIVACY

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

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

Users must agree **NOT** to use or store any of the following sensitive data in the UCH 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
- 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 any health-related and/or personally identifiable information (PHI/PII) must be marked as identifiable in the REDCap project and data containing PHI/PII should be de-identified before download and only downloaded to secure & encrypted computers that are approved by UConn, UConn Health, or your local institution. In the Move to Production form, users will have to provide justification for collecting identifiers in their project which will be reviewed in determining its admission. ***Collect only the minimum necessary PII/PHI and separate PII/PHI from study data and responses (de-identify).***

Data exported from REDCap projects shall comply with all IRB, Institutional Compliance, and Privacy, and Patient Data Governance deidentification parameters. Logs of data exports will be made available for verification against IRB-approved release and sharing of data upon request.

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

Users agree to encrypt and/or password protect information on electronic devices; agree not to download PHI/PII onto personally owned electronic devices; agree not to attempt to access information by using a user identification code or password other than their own; and to not release their user identification code or password code to anyone or allow anyone to access or alter information under my identity.

Users agree to take all reasonable precautions to safeguard confidential information and will ensure to use password-protected screen-savers and encrypted laptops, and never leave their computer open for others to view.

6. PROPER USE OF THE REDCAP SYSTEM

The UCH REDCap system consists of two separate environments, Development *(test/sandbox)* and Production. **ONLY the Production system can be used for live "real" data collection.** The Development *(test/sandbox)* system is strictly used for design, development, testing, and training with simulated mock data. Live data collection and/or storage of **"real" data is strictly prohibited in the Development system**. 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-**'. The PI must be listed as a user in the project in both systems. The PI information (name and email) and IRB approval number must also be listed on the project setup page. This information must match the approved IRB documentation.

When creating the REDCap project in development, the PI or designated project manager has full control over the design and setup. Through functionalities like survey creation, longitudinal project setup, repeating instruments and events, and advanced field specifications, REDCap projects can be designed in

multiple ways and for various types of research. Projects can utilize an unlimited number of forms/assessments/surveys/arms/events and are unrestricted in the amount of data storage that incurs. However, it is important to note that the study protocol determines what (and how) data can be collected. Project forms/instruments should match IRB-approved documents. Data that are not needed, or not in your approved protocol, should not be collected.

Allow plenty of time for project development, testing, and deployment. Be sure to thoroughly test (and retest) projects before requesting that they be moved into Production status. Test data should include different scenarios that will allow testing all possibilities with branching logic, calculated fields, survey invitations, etc., see Section 7 for training resources. Please note that Development system data **will not** be migrated to Production and will be deleted when your project is moved to Production.

To migrate projects from the Development to the Production system, the PI or their designated project manager must click the 'Move Project to Production' button at the bottom of the Project Setup page. The Move to Production Request form will open automatically. The requester must complete **all** the required information and provide the appropriate IRB documentation. Upon submission, the REDCap Administrator will begin processing the move to production. After it has been approved and moved to the production system by the REDCap Administrator, the PI, and the requestor will be added as users to the project. The REDCap Administrator will then ask the requestor to verify and inspect the project one last time in Production; upon confirmation, the project will be finalized in production status and the PI will be automatically notified. It is then the responsibility of the PI or their designated project manager for adding/removing additional users and assigning privilege access. If the project is using REDCap to collect PHI/PII, the PI must ensure that study personnel either entering or accessing data stored with REDCap have been given the appropriate authority to do so.

Once the project is in Production status, changes cannot be made in real-time to the project as it was in Development status. However, changes to the project may be made in DRAFT MODE, after which such changes will be reviewed and approved by a REDCap administrator. Once those changes are approved, you will then receive an email confirmation informing you that those changes have taken effect on your production project. Edits in Production should only be 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 should be tested in Development. Altering a project that is in Production and has data can cause data loss in some instances. If any critical issues are flagged, 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 before submitting changes. The impact on these fields will **NOT** be tested by the REDCap Administrator.

Users should protect their projects by making frequent backups of the project's data dictionary, particularly before and after any changes are made. The PI should also routinely back up their data via the Data Export tool.

REDCap project must be actively maintained per the timeframe described in the user's approved IRB protocol. The project end date listed on the Move to Production form should match the valid thru date on the IRB approval letter (if applicable). The PI or designated project manager is responsible for providing us with any updated approval letters, and/or informing us of project end-date changes.

REDCap is **NOT** to be used as for project or data storage beyond the active data collection. Once data collection is complete, please update the project status. Under the 'Other Functionality' tab of the project, put it in Analysis/Cleanup status. This will disable most project functionality, although all collected data will remain intact. You then want to export your data and project files. Once the data and project files have been exported/downloaded, you may mark the project as 'Completed' or 'Delete the Project'. Marking the project 'Completed' will take it offline and remove it from everyone's project list, after which it can only be seen again by clicking the *Show Completed Projects* link at the bottom of the *My Projects* page. Please note, once marked as Completed, no one in the project (except for REDCap administrators) can access the project, and only administrators may undo the Completion and return it back to an accessible state for all project users. Marking a project as Completed is typically only done when you are sure that no one needs to access the project anymore, and you want to ensure that the project and its data remain intact for a certain amount of time. Projects are only allowed to stay in 'Completed' (or 'Analysis/Cleanup') status for up to 3 months – they must be deleted from the system by that time (the REDCap Administrator will do so if not already done so by the project staff). All projects are still subject to REDCap fees until they are deleted from the system. And all projects must maintain valid IRB approval while they are in Analysis/ Cleanup or Completed status. For more information, please review: Exporting Data, Backing Up, and Deleting Your Project in REDCap .

7. SUPPORT SERVICE

REDCap usage is designed as a self-serve model. Users are responsible for their own training, project development, and testing of their own projects. Thus, we strongly encourage REDCap users to take full advantage of the free training materials and resources provided:

- REDCap Training Videos
- Clinical Research Centers REDCap webpage
- Help & FAQ via the top of the main REDCap page, and explanatory text on the REDCap pages

While we want to support our end users as much as possible, we have limits to the immediacy and type/amount of support we can provide. We implore users to try to resolve their issue(s) before requesting direct Administrator support. Once users have exhausted all the resources provided in the above sources, users may seek individualized support. However, please note that if your question(s) and/or needs are outside of our free support policy, additional fees may apply at an hourly rate of $75 (see Appendix B).

8. FEES AND PAYMENTS

All Projects (e.g., Classic, Longitudinal, Single-Site, Multi-Site, With or Without Surveys): $150 per project for the first year. After the first year, $75 annually. These fees will include hosting, storing, and upgrades.

Fees will be invoiced at the time of moving the project to production and billed on a yearly basis. Once your project has been deleted from the system, you will no longer be billed – please note refunds for partial year are not provided.

Additional support and add-on services are available at an hourly rate of $75. A minimum charge of 1/4 hour per service request applies. For these services, billing will be done at the end of the month the service was provided. Refer to Appendix B for the full fee schedule

Invoices will be generated in our CORES billing system, and you will receive a notification from the system. If you have not been set up in our CORES billing system, you will need to register. Payment is due within 60 days from the invoice date If payment is not received your REDCap project/s will be deactivated and user access will be suspended.

Fees are waived for projects that are **only** for current UConn undergraduate/graduate students and **solely** for the purpose of a thesis, dissertation, or capstone project, and is not grant-funded, and are not grant-funded.

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. UCH REDCap support service will provide you with advance notice of any changes in fees.

9. ADD-ON SERVICES

The PI, or their designator, must request authorization from the UCH REDCap system administration to use add-on services, such as the REDCap Mobile App or Twilio, for each REDCap project. Additional Terms of Use Agreements are required and will be provided at the time of the request.

Users of the Application Programming Interface (API) must understand the risks when using the API Token.

If needs for your project lie outside of our normal free support policy or for more customized individual help, you may request support from our consult services. Our consult services operate on a fee-per-hour basis. Some common use cases of our consultation services include:

- *Project Design Support:* Your team can describe or provide your protocol and we can consult with your team on designing your REDCap project and how it should be constructed in REDCap.
- *Project Development and Build Support:* Instead of having to learn and build your REDCap project, we will construct your REDCap project for you.
- *Database and Data Migration:* If you are wishing to move your database from one database structure to another, we can do the build and/or data migration for your archived data.

10. 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 UCH REDCap system establishes users' consent to all monitoring and logging of their activities.

REDCap Administrators will execute routine audits on the Development and Production systems. Monthly data cleaning will be conducted on the Development system to make sure that no real data is being captured. Periodic production system checks will also be conducted to ensure proper usage. We will contact users via email if further action and/or information is needed.

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11. CHANGES TO THE AGREEMENT

The CRC and AITS may revise the User Agreement (UA) from time to time and reserves the right to do so at their discretion. Typically, these changes are made to conform to current practices, comply with changing regulatory requirements, or other similar purposes. Updates made to the UCH REDCap User Agreement will be sent to current users via email when they are made. Your continued use of the UCH REDCap Service after 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@UCH.edu.

12. LIABILITY

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

13. 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. 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.

PA 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.

PA 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

14. YOUR AGREEMENT TO THE TERMS

By clicking "I ACCEPT" or otherwise accessing or using any of the UCH 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 UCH REDCap Services or access any content. The user's acceptance, or subsequent access/usage, signifies approval by the study PI.

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APPENDIX A - EXAMPLES OF HUMAN SUBJECT RESEARCH DETERMINATIONS

Per the revised version of 45 CFR 46 – Protection of Human Subjects, the following are not considered research per the regulation:

1. Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority stetting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Secondary research involving non-identified newborn screening blood spots is also not considered research.

For other scenarios, following are the definitions applicable to human subject research and examples of activities for which the IRB is often asked to make a determination. These examples are provided as guidance to demonstrate how the definitions may be applied to make a determination. These examples are not intended to be exhaustive in the amount of detail or types of activities. In all cases individual must also consider compliance with HIPAA. Appropriate supervision must be in place for student and resident projects.

Definitions to be Applied to the Examples:

Systematic Investigation: A formal scientific inquiry characterized by all of the following:

- the formulation of a hypothesis or experimental question
- the requirement of adherence to a predefined plan for the data collection and analysis
- the performance of data analysis to evaluate the hypothesis or experimental question
- the results of the inquiry are intended to be replicable

Generalizable Knowledge: Information resulting from a systematic investigation that has at least one of the following characteristics:

- it is intended to be disseminated to a broader external audience by means such as professional publication and/or formal presentation

- it may be applicable to circumstances other than those under which the systematic investigation was conducted

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Intervention: Includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: Includes communication or interpersonal contact between an investigator and a subject

Private Information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Identifiable Private Information: private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable Biospecimen: a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Human Subject: A living individual **about whom** an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

If you need additional guidance, please contact the IRB.

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APPENDIX B – SUPPORT SERVICES

UCH REDCap Support Services

	FREE	$150/Y1, $75 after Y1	$75/hr*
SERVICES			
Training Resources and Materals	✓	✓	
New User Account Processing	✓	✓	
Password Reset	✓	✓	
Access to Development System	✓	✓	
Access to Production System		✓	
Project Hosting (active projects only)		✓	
Routine System Backups		✓	
Software patches and upgrades		✓	
Project Moves to Production		✓	
Project Changes Review & Approval		✓	
Project Event/Instrument Mapping		✓	
Technical/Troubleshooting support			✓
Project builds and configuration			✓
Database Migrations			✓
Complex branching logic/calc			✓
Survey configuration			✓
Customized reports			✓
Hands-on Training			✓
Any other REDCap task that requires intervention by staff			✓
			*minimum 15 minute support billing

EXTRA	**COST**
External Modules Add-on (extend REDCap functionality; if available)	$75/one-time
Twilio Enabling/Configuration	$75/one-time