UCONN HEALTH REDCap User Agreement

(*version Aug 2026*)

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). UConn Health REDCap (UCH REDCap) is a secure, web-based platform designed to support data collection for research studies. Use of UCH REDCap is subject to this User Agreement, applicable federal, state, and local laws, UConn Health and University of Connecticut policies, and the REDCap License Terms.

2. Permitted Use and Project Eligibility

UCH REDCap is available to UConn Health and UConn Storrs Principal Investigators (PIs) and their research study teams for non-commercial research and approved non-research institutional purposes. It may not be used for commercial activities, industry-initiated clinical trials, direct clinical care, patient management, creation or maintenance of the legal medical record, or any other activity directly related to healthcare delivery.

Non-commercial research means research conducted without the primary intent of generating commercial profit or directly supporting the development, marketing, commercialization, or sale of a commercial product or service. **Non-research institutional purposes** means internal administrative, operational, quality assurance, or quality improvement activities that do not meet the federal definition of research and are not intended to generate findings for publication or broad dissemination.

3. UCH REDCap Environments

1. **REDCap Development:** Used to design, build, and test projects using simulated or mock data only. Live research data must not be collected, entered, or stored in this environment. Development project titles must begin with the prefix "Dev-."
2. **Tier I REDCap Production:** An on-premises REDCap instance that meets HIPAA security requirements and is appropriate for most research projects. The fee is $150 for the first year and $75 per year thereafter. Fees are waived for unfunded student projects.
3. **Tier II REDCap Production:** A REDCap instance that meets enhanced regulatory and security requirements, including 21 CFR Part 11 compliance. This environment is intended for projects requiring higher research compliance, including research registries, investigator-initiated FDA-regulated projects, and select approved non-research projects involving PHI or PII. The fee includes a one-time setup charge of $500, followed by a monthly fee of $200.

The UCH REDCap Administrator determines the appropriate Production environment for each project based on technical, regulatory, security, operational, and compliance requirements. This determination is subject to administrative review and approval. All decisions are final.

Figure 1 provides a visual summary of the user and project eligibility criteria for UCH REDCap, illustrating how projects are evaluated for appropriate use and placement within the available UCH REDCap environments.

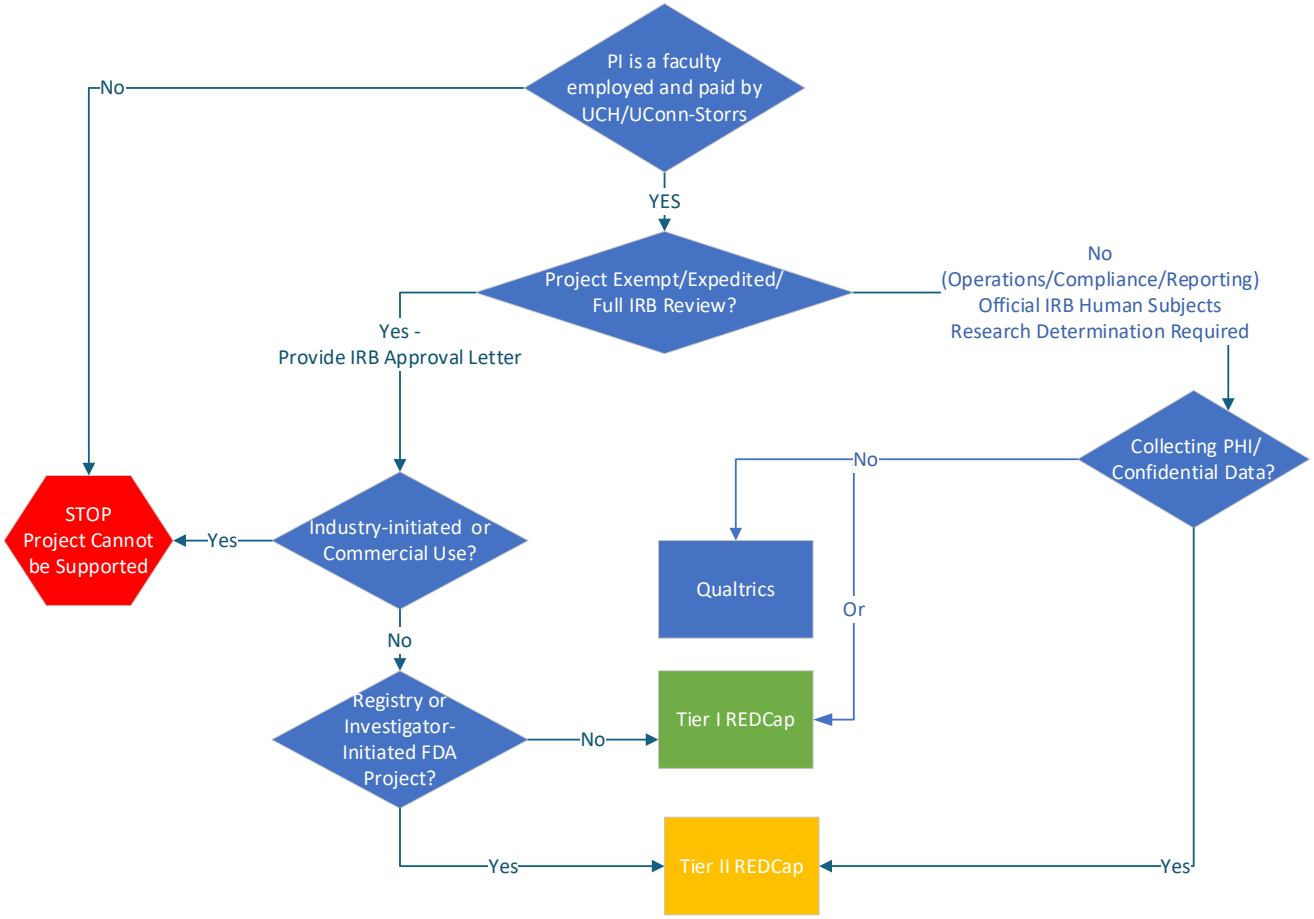

Figure 1. Project and user eligibility Rubric

4. Training, Support, and Consultation Services

All users must complete the introductory REDCap training modules before using UCH REDCap. Users are expected to make reasonable efforts to resolve questions through available training materials, user guides, knowledge base articles, instructional videos, and other UCH REDCap resources before requesting direct support.

UCH REDCap is provided under a self-service support model. The UCH REDCap Administrator provides administrative, technical, and operational support for the UCH REDCap platform but is not responsible for developing study databases, validating study-specific project designs, testing project logic, creating data collection instruments, or ensuring protocol compliance. These responsibilities remain with the Principal Investigator and project team.

Fee-based consultation services may be requested when a project's needs exceed standard support. Consultation services are billed at $72 per hour with a minimum billable increment of thirty minutes and may include project design consultation, project build assistance, database conversion, and data migration support.

5. Principal Investigator and Project Team Responsibilities

The Principal Investigator (PI) is ultimately responsible for each UCH REDCap project and all individuals granted access to it. The PI must remain listed as a project user in both Development and Production for the duration of the project. The PI's full name, email address, and IRB approval number must be entered accurately on the Project Setup page and must match applicable IRB approval, exemption, reliance, or

determination documentation.

The PI or designated project manager is responsible for project design, configuration, testing, validation, user access, data collection activities, protocol alignment, regulatory compliance, and ongoing project oversight. Project instruments, variables, workflows, surveys, forms, and data elements must conform to the approved study protocol and IRB documentation. Only information necessary to accomplish approved research objectives may be collected.

The PI or designated project manager must thoroughly test all project functionality before requesting Production migration, including branching logic, calculated fields, survey invitations, automated workflows, longitudinal events, repeating instruments, user rights, reports, and anticipated data entry scenarios. Failure to adequately test or validate a project is the responsibility of the project team.

6. Production Migration, Changes, and Project Lifecycle

After completing development and testing, the PI or designated project manager must request migration to Production through the "Move Project to Production" option on the Project Setup page. The request must include required IRB approval, exemption, reliance, or Human Subjects Research Determination documentation. Migration is subject to review and approval by the UCH REDCap Administrator.

Following migration, the requester must verify that the Production project accurately reflects the approved Development version. Once confirmed, the UCH REDCap Administrator will finalize the Production project and notify the PI that it is authorized for live data collection.

Once a project is in Production, direct modifications should be minimized and limited to minor corrections when possible. Significant changes to project structure, data collection instruments, variables, workflows, or other core functionality should first be developed and validated in Development. The PI and project team are responsible for evaluating the impact of proposed changes on data integrity, reports, logic, calculations, workflows, compliance, and scientific accuracy.

Projects must remain supported by current IRB approval, exemption, reliance documentation, or other institutional authorization. Updated approvals, amendments, closures, study end-date changes, and continuation documentation must be provided promptly. Failure to maintain current documentation may result in project suspension, deactivation, or removal.

UCH REDCap projects may remain in the UConn Health system only while they are supported by valid IRB approval or meet institutional retention requirements. Non-exempt studies must be removed when IRB approval expires unless updated continuation approval is provided in advance, while exempt studies must be removed upon study completion or after one year of data collection inactivity, whichever comes first. Student-led projects must be closed with the IRB and removed before the student graduates or leaves the institution to ensure continued oversight. If a Principal Investigator leaves UConn Health or UConn, their UCH REDCap projects must be removed once the study is closed with the IRB, unless the study will continue under another eligible PI with IRB-approved documentation transferring responsibility.

7. Billing and Fees

UCH REDCap project fees are assessed upon migration to Production and billed annually thereafter while the project remains active. Annual billing continues until the project is permanently removed from UCH REDCap. Refunds, credits, or prorated adjustments are not issued for partial billing periods or projects removed before the end of a billing cycle.

Invoices are generated and administered through the UConn Health Honeycrisp billing system. Users without

an established Honeycrisp account are responsible for completing required registration. . Failure to pay may result in project suspension or deactivation, suspension of user access, withholding of additional services, or other administrative action until the account is in good standing.

The CRC reviews the UCH REDCap Fee Schedule annually and may modify fees, billing practices, and service charges. Changes to annual project fees for existing projects become effective at the beginning of the next annual billing cycle, with reasonable advance notice.

8. Privacy, Security, and Data Governance

Use of UCH REDCap requires compliance with HIPAA, IRB requirements, data use and data sharing obligations, UConn Health policies, and all applicable laws and regulations. Users must collect, access, use, disclose, retain, export, and share only the minimum PHI or PII necessary for the approved research or institutional purpose.

Fields containing PHI or PII must be designated as identifiers in UCH REDCap. The PI or designated project manager must justify the need for identifiers, limit identifiers to the minimum necessary, separate identifying information from research data when practicable, de-identify exported datasets when identifiers are no longer required, and maintain appropriate administrative, technical, and physical safeguards throughout the project lifecycle.

Unless expressly authorized in writing and permitted by institutional policy, users may not collect, store, transmit, or maintain financial account numbers, Social Security numbers, medical record numbers, health plan beneficiary numbers, mother's maiden names, credential numbers, IP addresses, PCI data, vehicle identifiers, biometric identifiers, full-face photographs, audio or video recordings, unauthorized PHI, ITAR-controlled information, or any information prohibited by applicable law, policy, contract, sponsor requirement, or university requirement.

All exports, downloads, disclosures, and transfers of UCH REDCap data must comply with applicable IRB approvals, participant authorizations, data use agreements, data sharing agreements, HIPAA requirements, privacy and security regulations, UConn Health policies, and applicable standards for de-identification or limited disclosure.

9. User Accounts, Access, Monitoring, and Enforcement

Access to UCH REDCap is restricted to authorized users with a legitimate research or institutional need. Users must register with a valid UConn Health or University of Connecticut institutional email address. Personal email accounts are not accepted. Each account is issued to one authorized individual and may not be shared, transferred, loaned, or used by another person.

Users are responsible for maintaining the confidentiality of usernames, passwords, API tokens, and other credentials. Users must immediately report actual or suspected unauthorized access, credential compromise, token compromise, or other security incidents to the UCH REDCap Administrator or appropriate IT Security Team.

All UCH REDCap activity is logged and may be reviewed by UCH REDCap Administrators and authorized users with appropriate logging rights. UConn Health may monitor, review, and audit Development and Production systems, including project activity, data exports, and related user actions, to verify compliance with this Agreement, IRB approvals, institutional policies, and legal or regulatory requirements.

UConn Health may delay, deny, suspend, restrict, revoke, or terminate access to any UCH REDCap project, user account, add-on service, API, external module, or third-party integration that does not comply with this

Agreement, IRB requirements, institutional policies, security standards, operational requirements, or applicable laws and regulations. Action may occur without prior notice when necessary to protect institutional systems, research participants, or regulated information.

10. Add-On Services, APIs, and Third-Party Integrations

The PI or designated project manager must obtain prior approval from UConn Health REDCap Administration before enabling or using any UCH REDCap add-on service, module, plugin, API, external module, third-party integration, UCH REDCap Mobile App, Twilio, or similar service that accesses, transmits, stores, or processes project data.

Approval is subject to administrative, technical, security, privacy, and regulatory review and may require additional terms, service-specific agreements, Business Associate Agreements, or other documentation. API tokens must be treated as confidential credentials and must not be shared, embedded in unsecured applications, transmitted insecurely, or exposed in public repositories or other publicly accessible locations.

11. Acknowledgement, Liability, and Changes to this Agreement

By accessing or using UCH REDCap, users acknowledge that they have read, understand, and agree to be bound by this User Agreement. If a user does not agree or cannot comply, the user may not use UCH REDCap. User acceptance or continued access also signifies approval by the study PI.

Notwithstanding any other provision of this Agreement, CRC and AITS support staff shall not be liable for the negligence, misconduct, project design decisions, data collection practices, or regulatory compliance failures of project owners, PIs, project teams, users, or persons under their supervision.

The CRC and AITS may revise this Agreement from time to time to reflect current practices, regulatory requirements, operational needs, or similar purposes. Updates will be communicated to current users by email. Continued use of UCH REDCap after notice of changes constitutes acceptance of the revised terms. Questions may be directed to redcap@uchc.edu.

12. Publication Acknowledgement

Users must acknowledge the use of REDCap in publications, presentations, abstracts, dissertations, theses, and other scholarly works that use REDCap for data collection or data management. Recommended 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.”

13. Your Agreement to Terms (*for online version*)

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.