UT Health San Antonio
The University of Texas Health Science Center at San Antonio

REDCap End User Agreement

Research Electronic Data Capture (REDCap) is a secure, web-based electronic data capture tool hosted by the Department of Population Health Sciences (PHS). REDCap is a general system for creating screens for data entry, including rules to identify discrepant data and send alerts based on entered data. REDCap may also be used to create and administer surveys. REDCap is **not** an Electronic Health Record (EHR).

REDCap was developed by a multi-institutional consortium initiated at Vanderbilt University. REDCap is hosted through a partnership with PHS and Information Management Systems (IMS) at UT Health San Antonio (UTHSA).

I. User's Responsibility

The user agrees to the following terms:

a) The user agrees to and will abide by UT Health San Antonio Handbook of Operating Procedures (HOP) 5.8.10: Information Resources Acceptable Use And Security Policy.

b) The user will use, disclose, receive, transmit, maintain or create data consistent with all applicable guidelines and policies of UT Health San Antonio, state, and federal laws.

c) If the project and/or data managed by Clinical Research Informatics, to abide by the Clinical Research Informatics Data Use Agreement (**Appendix B**).

d) The user agrees to use REDCap to store data for single projects only. User will not mix data from various projects. Storing project data separately will allow the project administrator to access, analyze and successfully track project data.

e) If the project for which REDCap will be used is a cancer protocol that requires the approval of the Protocol Review Committee (PRC) at the Mays Cancer Center (MCC), the user will ensure that accruals are entered into the Information Data Exchange and Acquisition (IDEAS) accrual reporting system or Velos. In the event that accruals are not being directly entered into IDEAS or Velos, arrangements to report from REDCap can be made,

but the appropriate approved forms must first be implemented in the project before it is put into production.

f) The user understands that the Department of Population Health Sciences Clinical Research Informatics does not support use of REDCap for FDA-governed clinical trials as it is NOT 21 CFR Part 11 Compliant. Click here for more information if you are considering placing an FDA-governed study within REDCap.

g) The user understands that the Department of Population Health Sciences Clinical Research Informatics does not maintain a NIST 800-53 (Federal Information Security Management Act – FISMA) compliant REDCap system.

h) The user understands that PHS Clinical Research Informatics performs an audit and reviews all projects prior to moving projects to production.

i) The user understands that PHS will be required to make changes to the REDCap End-User Agreement as required by IRB, Institutional Compliance and Privacy, InfoSec, and Institutional Patient Data Governance. When these changes are made, the PHS will notify all current REDCap account holders and make a new copy of the REDCap End-User Agreement available for review. The user understands and agrees that if the user uses REDCap after the date on which End-User Agreement has changed, PHS will treat that as your use acceptance of the updated End-User Agreement.

II. Service Fees

a) The user understands the Clinical and Translational Science Award (CTSA), through the Institute for Integration of Medicine and Sciences (IIMS) subsidizes costs for basic services provided by REDCap administrators. Refer to **Appendix A** for full fee schedule.

b) The user understands there are currently no fees for storing data beyond the completion date of the project, but PHS reserves the right to assess such fees with proper advance notice, giving project owners adequate time to archive project data before the fees are charged. The user will be aware of the data storage and retention requirements of the institution, study sponsor, and federal agencies with oversight of the project. Because VA projects must store data for 6 years beyond the inactivation date, the STVHCS supplies PI folders where the data can be stored.

III. Confidentiality and Data Usage

a) Projects that include identifiable information and/or Protected Health Information (PHI) should utilize the coding functions within REDCap for the collection and storage of data.

i. NOTE: South Texas Veterans Health Care System (STVHCS) research data must be entered into UTHSA instance of REDCap in a coded manner for individual projects and any keys to coding systems must be stored behind the STVHCS firewall and not within UTHSA instance of REDCap.

b) 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 to the Institutional Compliance and Privacy Office (ICPO) for verification against IRB approved release and sharing of data upon request.

c) Access to REDCap projects will be configured by each project owner or by someone to whom the project owner grants user rights privileges. The user rights settings define all users, their project role and their access to specific aspects of REDCap functionality. If the project is using REDCap to collect PHI, the project owner must ensure that all study personnel either entering or accessing data stored with REDCap have been given the appropriate authority through the Office of Clinical Research. Access logs will be made available to the Institutional Compliance and Privacy Office (ICPO) for verification against approved study personnel upon request, as well as, to South Texas Veterans Health Care System (STVHCS) or University Health System (UHS) research and compliance personnel if applicable.

d) Users agrees not to share their login credentials with other study personnel working on the project in accordance with Handbook of Operating Policy (HOP), 5.8.10 *Information Resources Acceptable Use and Security Policy.*

e) The user agrees to encrypt and/or password protect information on electronic devices; agrees not to download identifiable patient information onto personally owned electronic devices; agrees not to attempt to access information by using a user identification code or password other than their own; and not release their user identification code or password code to anyone or allow anyone to access or alter information under my identity.

f) The user agrees to take all reasonable precautions to safeguard confidential information, and will ensure to use password protected screen savers, encrypted laptops, and to never leave their computer open for others to view UT Health San Antonio protected health information.

IV. Acceptable Use

a) The user understands that the Department of Population Health Sciences Clinical Research Informatics does not maintain a NIST 800-53 (Federal

Information Security Management Act – FISMA) compliant REDCap system.

b) The user understands that REDCap should not be utilized as an electronic medical record (EMR). The complexity of managing, supporting, and documenting clinical care is beyond the functionality of REDCap. Users must receive formal approval for a limited exception from the institutional Patient Data Governance Committee to utilize REDCap for charting data that may compromise any part of the patients' legal health record. Data considered part of the legal health record is subject to requirements for electronic exchange and information release at the direction of the patient. REDCap is not capable of performing these functions. For this reason, REDCap should not be utilized for the original (first) collection and management of data considered part of the legal health record.

c) The user understands that inappropriate system use may result in the loss of privileges including revocation or suspension of access.

V. Publication Requirements

Any publications resulting from the use of REDCap to collect and manage data should include the following citations:

Paul 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.

CTSA NIH Gran UL1-RR024982

VI. Termination

Upon termination of employment with UTHSA and/or upon completion of the research study, the user agrees to notify the primary contact/project manager within 24 hours so that the user account can be disabled/deactivated. The user understands there is no right to any ownership interest in any confidential information accessed or created by the user during and in the scope of employment with UTHSA.

In signing this agreement, the user agrees and understands the terms and conditions required under this RedCAP End User Agreement.

Appendix A

Activity	Fee
Initial project consultation for REDCap and/or REDCap survey (up to 60 minutes) Note: additional hours may be available for CTSA and Mays Cancer Center related projects.	No fee
Campus workshop training/Office hours	No fee
Individual hands-on Training session for REDCap and/or REDCap survey (up to 60 minutes)	$100
New REDCap project setup • Creation of new user accounts • Assignment of users to the project • Definition of user rights and data access groups	No fee
All other custom REDCap work • Data extraction • Survey creation • Case Report Form creation • Data migration	$75/hour

*Policies, guidelines, and fees are subject to change.
*Questions regarding this User Agreement should be sent to redcap@uthscsa.edu

Appendix B: CLINICAL RESEARCH INFORMATICS DATA USE AGREEMENT

[NAME OF REQUESTOR] ("Data Requestor") desires to perform a research study or project (as such term is defined in the Section below) using data provided from the University of Texas Health San Antonio (UTHSA) clinical data warehouse or information systems supported by UTHSA Clinical Research Informatics (CRI). UTHSA CRI is part of the Department of Population Health Sciences in the Joe R. and Teresa Lozano Long School of Medicine at UTHSA. Data Requestor hereby agrees and acknowledges that as a condition of performing the Project and receiving the requested data from CRI, the data requestor must comply with the terms and conditions of this Data Use Agreement (the "Agreement"). Data Requestor acknowledges that violation of this Agreement may subject them to sanctions including but not limited to loss of the privilege to requested data and/or institutional disciplinary action.

1. PROJECT SCOPE AND PURPOSE

A. Project Classification

This Agreement governs the collection of data by and management and disclosure of data to the Data Requestor for the project entitled "[NAME OF PROJECT or PROTOCOL]" (and if applicable: UTHSA IRB protocol: [PROTOCOL NUMBER]) (the "Project").

Research: If the project entails research involving human subjects as defined in Title 45 CFR Part 46, §46.102, it is the responsibility of the user to obtain appropriate IRB approval and to abide by all guidelines provided by the Institutional Review Board (IRB) and the institutions in which the research is being conducted [such as South Texas Veterans Health Care System (STVHCS) or University Health System (UHS)]. Failure to abide by the research plan as approved by the IRB and institutions may result in a determination of reportable noncompliance to institutional leadership, federal agencies, and study sponsors. Because privacy and confidentiality are considerations in human subjects' protection, plans for the collection, acquisition, use, release, and storage of identifiable data must be provided to the IRB and are included in IRB deliberations and decision-making. Changes in these plans may impact IRB decision-making and must be submitted to the IRB prior to implementation.

Research projects may also meet the following criteria and as such also require review and approval by the UTHSA Patient Data Governance Sub-committee:

- Collection, acquisition, use, and release of identifiable health information to outside entities for which a HIPAA Waiver has been granted and a data use or business associates' agreement is required,
- Acquisition, access, storage or movement of identifiable health information **outside** activities deemed Treatment, Payment or healthcare Operations (TPO) according to the regulations promulgated under the Health Insurance Portability and Accountability Act ("HIPAA"), i.e., Title 45 C.F.R. 160, 162, and 164 ("HIPAA Regulations") AND NOT specified in a HIPAA Authorization,
- Changes to existing storage, movement or security of identifiable health information
- Release, transmission or storage outside the UTHSA network NOT specified in a HIPAA Authorization,

- Data acquisition, access, use or release referred to the Patient Data Governance Sub-committee by clinical department chairs, institutional data stewards or institutional information system owners.

Non-Research: While projects deemed non-research are not governed by the common Rule (45 CFR part 46) and as such do not fall under the authority of the IRB, they may meet the criteria above and require review and approval by the UTHSA Patient Data Governance Sub-committee.

B. Data Classification

The Project data constitute [*will be populated electronically with either* "a Limited Data Set (LDS)" or "Individually Identifiable Health Information" *that are selected on the project form in REDCap*]. Both a LDS and individually identifiable health information are considered Protected Health Information (PHI) under the HIPAA Regulations. These terms are defined in the HIPAA regulations.

C. Assurances

The Data Requestor certifies and represents their understanding and agreement that the data provided under this agreement are classified as [*will be populated electronically with either* "a Limited Data Set (LDS)" or "Individually Identifiable Health Information" *that are selected on the project form in REDCap*].

The Data Requestor certifies and represents their understanding that this agreement applies in full regardless of the classification of the data set as Individually Identifiable Health information or a LDS under HIPAA.

The Data Requestor certifies and represents that they possess the competencies necessary to collect, maintain, use, store, transmit or otherwise disclose project data according to this agreement, the HIPAA Privacy and Security Regulations, or as otherwise required by other State, institutional policy, applicable law or regulation. Laws, regulation and regulatory guidance are amended from time to time. This agreement survives all such amendments and will apply to the effective law and regulation at the time of future application.

Data Requestor certifies and represents that the Data Requestor has sufficient scientific knowledge, skill, and experience in the subject matter of the Project to assure that the data requested are limited in scope to the minimum information necessary to conduct the Project.

The Data Requestor agrees to use or disclose the data only for the limited purpose of the Project.

The Data Requestor agrees that individuals permitted to use or receive identifiable data for purposes of the Project are limited to the individuals or "project team members" listed in the /Institutionalapproved protocol personnel form (where required) or listed on the Institutional Data Acquisition, Access, Use and Release (DAUR) request form (where required). If neither is applicable, the Data Requestor

agrees to the principle of Minimum Necessary in limiting access to the data to those for which such access is necessary to fulfill their role on the project.

The Data Requestor certifies and represents their understanding that **this is an internal UTHSA Data Use Agreement (DUA) and that as such, disclosure, access and transmission of project data to individuals outside UTHSA are strictly prohibited without an external DUA.**

2. DATA REQUESTOR DUTIES

Data Requester hereby agrees:

A. To use, disclose, receive, transmit, maintain or create data consistent with all applicable guidelines and policies of UTHSA, state, and federal laws.

B. To fully comply with the requirements of HIPAA, including without limitation, 45 C.F,R. 160, 162, and 164, throughout the term of this Agreement. Data Requestor will not (and will ensure that any project team member does not) use or disclose the data in any manner that would violate the requirements of HIPAA.

C. To maintain current knowledge of applicable law, regulation and regulatory guidance.

D. Not to use or disclose the data except as permitted under this Agreement. Without limiting the foregoing, Data Requestor agrees to use the data only for bona fide project purposes and to not use the data for competitive institutional or individual advantage. Data Requestor agrees to retain control over the resulting data, to limit use and disclosure of the data to the project team members for the purpose described above, and to use appropriate administrative, physical and technical safeguards, sufficient to comply with HIPAA and UTHSA security requirements as well as prevent any use or disclosure other than as provided for by this Agreement. The Data Requestor agrees to refrain from any attempt to identify the information or contact the individuals not explicitly stated in and authorized by IRB or Data Governance approval. Data Requestor agrees to data destruction requirements as per the Project IRB protocol, as specified on the DAUR form, sponsor or regulatory requirements, or is otherwise stated in this agreement when the data is no longer needed. Data Requestor agrees not to share any data with parties or individuals outside the employ of The University of Texas Health San Antonio without a separate data use agreement approved and signed by The Office of Sponsored Programs.

E. Not to share or allow someone else to use their user ID or password for data download. Data Requestor will not disclose the data to any person or entity except the project team members.

F. Not to collaborate or allow collaboration with a for profit entity by providing access to or use of the data, except with the prior written agreement approved and signed by The Office of Sponsored Programs.

G. To immediately report known or suspected privacy incidents in writing, and within 24 hours from the date of the incident, to UTHSA's Privacy Board and Institutional Compliance and Privacy Office of any (i) existence, use or disclosure, inadvertently or otherwise, of direct identifiers (as defined by HIPAA in 45 C.F.R. 164.514(e)(2) that were included in the data, and any (ii) use or disclosure of the data not permitted by this Agreement. At UTHSA, the Institutional Review Board serves as the Privacy Board for research projects and Institutional Compliance and Privacy Office (ICPO) serves as the Privacy Board for all other matters.

H. Not to disclose the data on the basis that such disclosure is required by law without notifying UTHSA's Privacy Board prior to any disclosure and receiving institutional approval for such disclosure.

I. To acknowledge support in all oral and written presentations, disclosures, and publications resulting from any use of the data.

i. A sample statement to be used in acknowledging use of Clinical Data Warehouse data is "This work utilized the Clinical Data Warehouse at the University of Texas Health San Antonio, via protocol number _____ (alternatively if applicable, via institutional Data Governance approval). The UTHSA Clinical Data Warehouse is supported by institutional funding and by the following: Patient-Centered Outcomes Research Institute (PCORI) Program Award (#CDRN-1306-04631); Accrual to Clinical Trials (ACT), through Grant #5ULTR001857; the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1 TR002645. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

ii. A sample statement to be used in acknowledging use of CRI provided Information systems such as REDCap or IDEAS is, ""This work utilized information systems provided through Clinical Research Informatics at the University of Texas Health San Antonio, via protocol number _____ (alternatively if applicable, via institutional Data Governance approval). These information systems are partially supported by institutional funding and by the following: the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1 TR002645, and for Cancer Investigators the Mays Clinical Cancer Center through Grant P30 CA054174-21. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH."

I. If a Limited Data Set, not to identify, or attempt to identify, the Individuals (as such term is defined under HIPAA) contained in the data by any means, or to contact, or attempt to contact, any Individual whose information is contained in the data.

J. To immediately destroy or return any data which comes into Data Requestor's possession which Data Requestor is not authorized to possess pursuant to the terms of this Agreement.

K. To not use the data or other information obtained through this agreement to make clinical or medical decisions.

L. To not, under any circumstance, sell the data or access to the data obtained under this agreement.

M. Data Requestor will indemnify and hold harmless the institution from liability and claims arising out of a breach of this Agreement including but not limited to an unauthorized use or disclosure of the data. If the Data Requestor is subject to, or their actions are covered under, a federal or state tort claims act then liability will be limited to the applicable federal or state tort claims act.

3. TERM; TERMINATION

A. Term. This Agreement is effective as of the date last signed below and will continue until the data are destroyed by the requestor.

B. Termination. This Agreement may be unilaterally amended or terminated at any time by CRI of UTHSA institutional offices including but not limited to the IRB, Institutional Compliance and Privacy Office, or Office or Sponsored Programs in the event that Data Requestor breaches or violates a material term of this Agreement.

C. Disposition of Records. Upon expiration or termination of this Agreement, Data Requestor will return or destroy any data accessed pursuant to the Project IRB protocol, Determination, Data Governance Approval or the applicable UTHSA policy regarding data retention. The protections set forth in this Agreement shall be extended so long as Data Requestor holds such information. This section will survive termination of this Agreement.

4. MISCELLANEOUS TERMS

A. Publication. Data Requestor agrees that research study or project publications arising from the use of the data will contain only aggregate data that are not capable of identifying any Individual whose data or information is received pursuant to this Agreement unless a specific authorization is obtained from the Individual and covered under HIPAA. Direct identifiers are defined by HIPAA in 45 C.F.R. 164.514(e)(2). In general, unless otherwise certified by the Data Requestor, table or figure “cell sizes” containing less than 10 individuals should be reported as “< 10” to avoid potential for identification.

B. Data Quality. [*will be populated with one or more of the options below if checked on the project form in REDCap*]

☐ B.1 The requested data include data captured during routine care. The requestor understands that the accuracy of routine care data generally cannot be measured at the time of secondary data use. The data warehouse does not “clean” or otherwise attempt to change or correct data captured during routine care. Known

problems with the data will be reported to the Data Requestor at the time of the request. The fitness of the data for project use and claims made based on analysis of the data always remain the responsibility of the data Requestor.

☐ B.2 The requested data include data entered or otherwise managed by the requestor or individuals under their supervision. The accuracy and fitness of data entered or otherwise managed by the project team and claims made based on analysis of the data always remain the responsibility of the requestor and individuals under their supervision.

☐ B.3 The requested data include data for which the CRI has agreed to data quality assurance or assessment activities in the project Scope of Work. The data quality assurance or assessment activities and their limitations are documented in the Scope of Work and have been explained to and accepted by the requestor. If repeated data quality assessment activities using the same method and on a random sample the size of which is agreed in the Scope of Work do not fall within the originally agreed acceptance criteria, where possible, the data will be remediated by CRI until the specified measures meet the acceptance criteria agreed in the Scope of Work or another mutually agreeable resolution is reached. The fitness of the data for project use and claims made based on analysis of the data always remain the responsibility of the requestor and individuals under their supervision.

C. Third Party Beneficiaries. UTHSA is a third-party beneficiary of this Agreement and is entitled to enforce any obligation or responsibility of the Data Requestor pursuant to this Agreement.

D. Signature. The signature below constitutes acceptance and agreement to the terms of this Agreement. Data Requestor will not, at a later date, repudiate the meaning of the signature or claim that the signature is not legally binding. A printed copy of an electronically signed Agreement will be deemed an original.

ACCEPTED AND AGREED:
Data Requestor
BY:

_____
(Signature) (Date)
Name:
Title:
Department:
Email: