



Research Electronic Data Capture (REDCap) is a secure, web-based electronic data capture tool hosted by the Department of Epidemiology and Biostatistics (DEB) and was developed by a multi-institutional consortium initiated at Vanderbilt University.

REDCap is hosted through a partnership with DEB and Information Management Systems (IMS) at UT Health San Antonio (UTHSA). Currently, 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.

In signing this agreement the user is agreeing to the following:

1. To use, disclose, receive, transmit, maintain or create data consistent with all applicable guidelines and policies of UTHSA, state, and federal laws.
2. If the project for which REDCap will be used involves human subjects research (per the U.S. Department of Health and Human Services [DHHS] Code of Federal Regulations definition<sup>1</sup>), 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 guidelines approved by the IRB for your protocol; to include collection, use, storage, and access to identifiable data may result in a determination of reportable noncompliance to institutional leadership and federal agencies.**
3. To collect, use, and maintain such data according to the Privacy Regulations and the Security Regulations under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations and guidance, all as amended from time to time (“HIPAA”) and the Health Information Technology for Economic and Clinical Health Act, as incorporated in the American Recovery and Reinvestment Act of 2009, and its implementing regulations and guidance issued by the Secretary, all as amended from time to time (“HITECH Act”).
4. The user understands that he/she must follow all applicable UTHSA, state, and federal guidelines and policies for the collection of Protected Health Information (PHI).
5. Projects that include identifiable information and/or PHI should utilize the

coding functions with REDCap for the collection and storage of data. NOTE: VA research data must be entered into REDCap in a coded manner for individual projects and any keys to coding systems must be stored behind the VA firewall and not within REDCap.

6. Data exported from REDCap projects should be limited to deidentified data. Logs of data exports will be made available to Office of Regulatory Affairs & Compliance (ORAC) for verification against IRB approved release and sharing of data upon request.
7. Access to REDCap projects is configured by each project owner or someone the project owner grants user rights privileges to. 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 IRB. Access logs will be made available to Office of Regulatory Affairs & Compliance (ORAC) for verification against approved study personnel upon request, as well as, to STVHCS or UHS research and compliance personnel if applicable.
8. To store data for a single project and to not mix data from various projects so that access to the data can be successfully tracked and analyzed by the administrator for the project.
9. 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), it is the responsibility of the user to 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.
10. The Department of Epidemiology and Biostatistics Information Systems does not support use of REDCap for FDA-governed clinical trials. Click [here](#) for more information if you are considering placing an FDA-governed study within REDCap.
11. Users will not share their login credentials with other study personnel working on the project.
12. The user agrees to the fee schedule described in Appendix A, and understands the biostatistician and data analysis fees are not included.
13. Currently there are not fees assessed for storing data beyond the completion date of the project but DEB 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. Ensure you are 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.
14. The user understands that DEB IS staff is available to perform an audit and review of projects prior to moving projects to production.
15. The DEB may make changes to the REDCap End-User Agreement from time to time. When these changes are made, the DEB will make a new copy of the REDCap End-User Agreement available at [http://deb.uthscsa.edu/files/REDCap\\_End\\_User\\_Agreement.pdf](http://deb.uthscsa.edu/files/REDCap_End_User_Agreement.pdf) You

understand and agree that if you use REDCap after the date on which End-User Agreement has changed, the DEB will treat your use as acceptance of the updated End-User Agreement.

16. *I understand that inappropriate system use may result in the loss of privileges including revocation or suspension of access.*

17. **Upon Termination:** User agrees that upon termination of my employment with UTHSA and or upon completion of the research study, I agree to notify the primary contact/project manager within 24 hours so that my user account can be disabled/deactivated. I understand that I have no right to any ownership interest in any confidential information accessed or created by me during and in the scope of my employment with UTHSA.

18. 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.*

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## 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 <ul style="list-style-type: none"> <li>• Creation of new user accounts</li> <li>• Assignment of users to the project</li> <li>• Definition of user rights and data access groups</li> </ul>	No fee
All other custom REDCap work <ul style="list-style-type: none"> <li>• Data extraction</li> <li>• Survey creation</li> <li>• Case Report Form creation</li> <li>• Data migration</li> </ul>	\$75/hour

\*Policies, guidelines, and fees are subject to change.

\*Questions regarding this User Agreement should be sent to [redcap@uthscsa.edu](mailto:redcap@uthscsa.edu)