**REDCap Text for IRB and/or Grant Submission**

Study data will be collected and managed using REDCap (Research Electronic Data Capture).  REDCap[1] is a secure, web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).  REDCap also provides a powerful tool for building and managing online surveys. The research team can create and design surveys in a web browser and engage potential respondents using a variety of notification methods. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the system owner. The iterative development and testing process results in a well-planned data collection strategy for individual studies. REDCap provides a secure, web-based application that is flexible enough to be used for a variety of types of research, provide an intuitive interface for users to enter data and have real time validation rules at the time of entry. The system was developed at Vanderbilt University but is now part of an international and multi-institutional consortium which includes The University of Alabama at Birmingham (UAB). REDCap has been disseminated for use locally at other institutions and currently supports 4,000 academic/non-profit consortium partners in 135 countries on six continents and over 1.2M research end-users ([www.project-redcap.org](http://www.project-redcap.org)).

REDCap system is centrally hosted in UAB Department of Medicine (DOM) secure data center. DOM has full time professional staff to support the infrastructure and application. DOM REDCap servers are role specific and reside in a secure Virtualized environment, which is behind an enterprise grade Palo Alto firewall. Only IRB approved research team members will have access to the REDCap system. Each team member will be granted access to the REDCap data system through a secure and unique login. The database and the associated components are also part of a redundant backup strategy. Network transmissions (data entry, survey submission, web browsing, etc.) in REDCap are protected via Secure Sockets Layer (SSL) encryption. DOM IT is the largest and most trusted provider of REDCap at UAB. The award winning and widely followed implementation is in accordance to NIST 800-53/800-171 (HIPAA) and FDA CFR21 part 11 guidelines and has been thoroughly vetted by external/third-party security companies and approved by all authorizing parties at UAB. DOM REDCap is also the only instance by far to have received an authorization to operate (ATO) from NIH/NHLBI and pending FDA approval.

**Publications:**

[1] P.A. Harris, R. Thielke, R. Taylor, J. Payne, N. Gonzalez, J.G. Conde. Research Electronic Data Capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support. Journal of Biomedical Informatics, 2008.

**Citing REDCap**

Study data were collected and managed using REDCap electronic data capture tools hosted at UAB Department of Medicine.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.

1PA 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.*

2PA 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]*

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