



TraCS Clinical Research Data Management Service



The TraCS Clinical Research Data Management Service is a key initiative of the Biomedical Informatics core of the UNC-Chapel Hill CTSA. The purpose is to provide a system, and associated support resources, to enable efficient and high quality collection and management of research data that is standards-based in design, development and implementation.

Standard features of electronic clinical research data management systems are available in the web-based systems provided with the service. These include interactive data entry with real-time field validation, lab data imports, audit logs to record database modifications, database integrity checks, security (in logins, permissions based on need, and encryption), reporting, forms inventory, and exports to common statistical packages for analysis.

Logging tracks all data entered in REDCap so that it can be traced back to the person who entered it. No data can be changed without showing who has made the changes. This allows the study team to ensure the security and integrity of the data collected and submitted; therefore, there are controls surrounding this aspect.

REDCap also provides for principle investigator sign-off on data, as required in FDA studies. Although users

can modify data based on their permissions, they cannot delete the subject or history of that subject. Requests to delete a subject must be made to the REDCap system administrator.

Our database system provides for secure web-based data entry with the data stored on servers that we maintain. The data is encrypted during transmission. The servers are located in a secure campus area with all appropriate physical security measures in place. The web and database servers are monitored by the TraCS IT staff, patched frequently, and scanned by a third party vendor to ensure that they are protected against known vulnerabilities. The scanning application is the standard service for the entire campus. Access is by individual user id, and is restricted to the forms and/or functions that the user needs to have.

The applications themselves are written using open source tools, and have also been scanned by the campus security office to ensure that the applications are also protected from known exploits. The data is backed up to electronic media on a daily basis. The electronic media is secured by ITS stored in a secure area separate from the servers.

Please cite both the NC TraCS Institute and the REDCap development team in any publications.

TraCS Researchers and Grant Pilot Awardees

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REDCap Development Team

Harris, P. A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J. G. (2009). Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics*, 42(2), 377-381.