

Appendix A: Boilerplate language for inclusion in grants and IRB documentation

Example 1: Grant submission when planning to use REDCap for research data management:

The ICTR Research Informatics Core (RIC) will be used as a central location for data processing and management. Vanderbilt University, with collaboration from a consortium of institutional partners, has developed a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. REDCap (Research Electronic Data Capture) 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 RIC. The iterative development and testing process results in a well-planned data collection strategy for individual studies. The REDCap Survey is 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. Both REDCap and REDCap Survey systems provide secure, web-based applications that are 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 (with automated data type and range checks) at the time of entry. These systems offer easy data manipulation with audit trails and reporting for reporting, monitoring and querying patient records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

Example 2: For inclusion into IRB submission

The ICTR Research Informatics Core (RIC) will be used as a central location for data processing and management. Vanderbilt University, with collaboration from a consortium of institutional partners, has developed a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. REDCap (Research Electronic Data Capture) 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 RIC. The iterative development and testing process results in a well-planned data collection strategy for individual studies. REDCap servers are housed in a data center at Einstein and all web-based information transmission is encrypted. REDCap was developed specifically around HIPAA-Security guidelines and is recommended to researchers at various institutions by both Privacy Offices and Institutional Review Boards. REDCap has been disseminated for use locally at other institutions and currently supports over 200 academic/non-profit consortium partners on six continents and over 20,000 research end-users (www.project-redcap.org).