The following content may be used in your IRB application or grant application if you are planning to use REDCap:

Study data will be collected and managed using REDCap (Research Electronic Data Capture). REDCap is a secure web application designed to support data capture for research studies. It provides user-friendly web-based case report forms, real-time data entry with branching logic and validation (e.g. for data types and range checks), audit trails, a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus), procedures for importing data from external sources, and advanced features such as a data quality check module. The system was developed by a multi-institutional consortium initiated at Vanderbilt University.

REDCap servers are physically located in the University of Michigan Medical School Information Systems (MSIS) data center. Application and database servers are on virtual machines (VM). The VM servers are Red Hat Enterprise Linux Server 5.6 (64-bit, 2.6.18 238 e15-smp kernel) 2x AMD Opteron 6174 5.0.95 2.2 GHz with 4 GB RAM, running Apache 2.2.3 (application servers) and MySQL (database servers). Physical security for the databases is provided in a professionally managed and equipped tier-2 data center with tightly controlled access. Remote data access employs SSL encryption and 2-tier Kerberos/Level 1 and UMHS Level 2 password challenges via LDAP authentication. Access to the application, the database, and the underlying systems infrastructure are consistent with industry best practices including HIPAA security and privacy requirements and the HITECH Act. The application provides audit trails on user access to MICHRS and MSIS technical and support teams. Backup of data is managed by MSIS and vulnerability testing is performed regularly by the University of Michigan Health System Medical Center Information Technology. Risk evaluation is performed using a methodology derived from NIST Special Publication 800-53 – “Recommended Security Controls for Federal Information Systems” and is used to refine and improve operating policies and procedures.

Daily backups and VM snapshots of the application and database servers are stored on a remote storage device. The restoration of the servers from a hardware or software failure are protected for 24 hours of disaster recovery.

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. This iterative development and testing approach results in a well-planned and implemented data collection strategy for individual studies. REDCap is flexible enough to be used for a variety of research types including multi-site clinical research trials, and provides an intuitive user interface for database design and data entry.