The Ohio State University Electronic Data Capture (EDC) core, housed within the Department of Research Information Technology (RIT) with major support from the Clinical and Translational Science Institute (CTSI), will be utilized as a central provider for this project's Electronic Data Capture (EDC) support. The Ohio State EDC core utilizes REDCap (Research Electronic Data Capture) as its primary EDC platform which will be adopted for this project. REDCap has been developed by Vanderbilt University, with collaboration from a consortium of institutional partners (including Ohio State), as a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. The REDCap platform is a secure, web-based application flexible enough to be used for a variety of types of research, provides an intuitive interface for users to enter data, and enforces real time validation rules (with automated data type and range checks) at the time of entry. This platform provides an intuitive data manipulation interface, custom reporting capabilities, audit trail functionality, and real-time data monitoring/querying of participant records. REDCap has multiple data export options to common statistical packages (SPSS, SAS, Stata, R).

REDCap is a powerful tool for building and managing online surveys and electronic data capture. The research team can create and design surveys and forms in a web browser and engage potential respondents using a variety of notification methods. REDCap data collection projects rely on a study-specific data dictionary defined in an iterative self-documenting process. The iterative development and testing process results in a well-planned data collection strategy for individual studies. The project specific data dictionary is defined by the research team with assistance available from EDC staff. REDCap supports electronic signatures by positively identifying the user through a unique username and password combination.

REDCap employs a robust multi-level security system that enables researchers to easily implement "minimum necessary" data access for their research staff, including specification of data fields that are identifiers. This feature includes "single click" ability to provide completely deidentified (removing all identified data fields and shifting dates) for analysis or other purposes. User activities are logged to enable auditing of all data access. Study data containing protected health information (PHI) is secured in accordance with The Ohio State University Wexner Medical Center procedure and user accounts are created and authenticated by RIT. Providing authorization (e.g., access to specific projects, user rights within the project, etc.) for all projects is managed by the project's owner.

Based on the EDC requirements outlined for this project, REDCap is recommended as an appropriate and reliably effective tool. Members of the EDC team are available to facilitate the creation and support of a project-specific database utilizing the REDCap data collection platform. Ohio State, through the CTSI, is an institutional partner of the REDCap consortium, which will allow the project to access and utilize this software application via the Ohio State hosted installation. The informatics support for the project will include access to, configuration of, and support for the REDCap web-based research data collection platform. Support will also be available for REDCap data collection instrument design on an as requested basis. In addition, RIT maintains expertise in a variety of informatics domains including software design and engineering, data integration, and data security. If informatics support needs arise during the project lifecycle, RIT may be used as a support resource under various funding models. The overall expertise and technologies offered by EDC Core are ideally suited to collaboratively support this project's needs.