**Boilerplate Language for Using REDCap in REB Applications**

REDCap has already been cleared by University of Windsor REB, so the line below will suffice for explanation:

**Data for this study will be collected, recorded, and stored using REDCap (Research Electronic Data Capture).**

If, however, you require additional language for any other reason, you can utilize the additional language below.

REDCap is a secure, web-based application that is flexible enough to be used for a variety of research, quality improvement and operational support projects. It includes features for PHIPAA compliance including real-time data entry validation (e.g., for data types and range checks), a full audit trail, user-based privileges, de-identified data export mechanism to statistical packages (SPSS, SAS, Stata, and R). 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.

All users are given individual user IDs and passwords and their access is restricted on a role-specific basis. Projects are managed by the owner of the project, and they are responsible for ensuring appropriate access to study data via the User Rights Module. REDCap is hosted on a virtualized Linux server by the IT Services Department at the University of Windsor. The server is subject to the University's Patch Management Policy and is closely monitored for security and performance. To enhance security, Managed Cortex XDR is employed to detect and respond to any security issues that may arise.

In the event of any data loss or system failure, the server is backed up using Dell PPDM. Additionally, the database is backed using zManda ZRM Enterprise, ensuring that the server and the data it contains are secure and can be made available in the event of a system issue.

**Boilerplate Language for Using REDCap in Grant Applications**

The WE-SPARK Health Institute administrated instance of REDCap (Research Electronic Data Capture), housed at the University of Windsor, and maintained by University of Windsor Information Technology Services will be used for this proposed project. REDCap has been developed by Vanderbilt University, with collaboration from a consortium of institutional partners (including UWindsor), 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/S-Plus).

REDCap data collection projects rely on a study-specific data dictionary defined in an iterative self-documenting process. The project specific data dictionary is defined by the research team with assistance from WE-SPARK REDCap Administrator when applicable. As part of the data dictionary development process, individual fields can be denoted as identifiers. When exporting a de-identified dataset, these variables are omitted. Additionally, the data export tool allows for the shifting/removal of dates. REDCap supports electronic signatures by positively identifying the user through a unique username and password combination. The provisioning of authorization (e.g., access to specific projects, user rights within the project, etc.) for all projects is managed by WE-SPARK Admin Super Users in conjunction with the project Primary Investigator (PI).

Based on the Electronic Data Capture (EDC) requirements outlined for this project the WE-SPARK Health Institute staff have recommended REDCap as an appropriate and desirable tool. Members of the EDC team will facilitate the creation and support of a project-specific database utilizing the REDCap data collection platform. University of Windsor, through the WE-SPARK Health Institute, is an institutional partner of the REDCap consortium, which will allow the project to access and utilize this software application via the UWindsor 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 as well as data Extract/Transform/Load (ETL) processes on an as requested basis. The WE-SPARK Health Institute, an institute created through a formal partnership between Windsor Regional Hospital, St. Clair College, Hotel Dieu Grace Healthcare, and the University of Windsor, maintains expertise in a variety of informatics domains including software design and engineering, data integration, and data security. If unanticipated informatics needs arise during project execution the WE-SPARK Health Institute can leverage existing local expertise to support the project.

Based on the scope of work for this project it is anticipated that these services will require approximately $xx,xxx of informatics consultation/implementation effort over the course of the project. The overall expertise and technologies offered by the University of Windsor and WE-SPARK Health Institute are ideally suited to collaboratively support this project needs.

**Boilerplate language for Informed Consent Forms (ICF) – No Identifiers**

This study will collect data using Research Electronic Data Capture (REDCap) software. REDCap is a secure web application for building and managing online surveys and databases created by Vanderbilt University.

REDCap servers are securely housed in an on-site limited access data center managed by the University of Windsor Information Technology Services. The data is all stored on a private, firewall-protected network. All users (including the researchers conducting this study) are given individual usernames IDs and passwords, and their access is restricted on a role-specific basis.

Only the research team will have access to information that identifies you to carry out this research study. If your study record requires an ID, the study team will generate a unique study ID that does not contain any identifying information. We will be storing “de-identified” study data under this unique ID in REDCap. Any identifying information is stored separately outside of REDCap. Only approved members of the research team will have access to your REDCap data.

**Boilerplate language for Informed Consent Forms (ICF) – Identifiers**

This study will collect data using Research Electronic Data Capture (REDCap) software. REDCap is a secure web application for building and managing online surveys and databases created by Vanderbilt University. REDCap is administered by the WE-SPARK Health Institute. WE-SPARK Health Institute is an innovative partnership between Hôtel-Dieu Grace Healthcare, St. Clair College, University of Windsor, and Windsor Regional Hospital that brings together health research strengths, expertise, and infrastructure from across the Windsor-Essex region of Ontario, Canada.

REDCap servers are securely housed in an on-site limited access data center managed by the University of Windsor Information Technology Services. The data is all stored on a private, firewall-protected network. All REDCap users are given individual usernames IDs and passwords, and their access is restricted on a role-specific basis.

This study will be collecting and storing identifying information for project administration purposes **[detail identifiers here and rationale as to why they are included]**. Only the research team and REDCap Super Users will have access to information that identifies you to carry out this research study. Upon completion of data collection, all identifying information will be removed.

REDCap Super Users (administrators who oversee day-to-day REDCap operations and monitor for appropriate REDCap usage) have access to all REDCap projects and their data. Super Users audit REDCap projects to ensure adherence to the Terms of Use and to Ethics Board approvals. They may come across identifying information during and audit or while assisting the research team with their project. All REDCap administrators have signed an agreement that ensures they will maintain confidentiality and breaking this trust may be grounds for dismissal and prosecution.