REDCap Terms of Use

WE-SPARK Health Institute, in joint effort with University of Windsor Information Technology Services (ITS) and in consultation with the Office of Research Ethics/REB, provides access and administrative support for Research Electronic Data Capture (REDCap). REDCap software is developed and updated by Vanderbilt University (www.projectredcap.org).

REDCap is a secure, web-based application used for building and managing online surveys and databases. It is a Personal Health Information Protection Act (PHIPA) compliant data capture tool that is specifically geared to support online or offline data capture for research studies and operations. REDCap has been implemented in a secure, controlled, and validated environment within the University of Windsor ITS infrastructure.

To comply with the End-User License Agreement (EULA) terms from Vanderbilt University, we need to ensure that:

- Only WE-SPARK Researchers, external sponsored collaborators and approved research personnel may access and use REDCap.
- REDCap is not to be used for any commercial purposes.

By requesting REDCap access and using REDCap, you are agreeing to the following terms. Please read them carefully:

1. **General**

    1.1. You will act in accordance with all applicable rules and regulations set forth by WE-SPARK Health Institute, University of Windsor ITS, your REB of record and any relevant institutional policies.

    1.2. If your REDCap project is used in a multi-institutional research study, appropriate data-sharing agreements should be in place before any data collection can occur. It is the responsibility of the REDCap user to ensure appropriate data-sharing and/or information management agreements are in place.

1.3. Unauthorized use of copyrighted material in REDCap projects is prohibited.

1.4. If there is suspicion that REDCap is being used for inappropriate or illegal activities that violate the EULA between University of Windsor and Vanderbilt University, your account may be suspended pending an investigation by a REDCap Administrator.

1.5. If you are using REDCap for operational support, quality improvement, or administrative purposes, you may not require REB clearance. Please consult with your Institutional REB or REB of record on whether clearance is needed.

2. Confidentiality

2.1. WE-SPARK Health Institute strongly discourages storage of identifiers in a REDCap project.

2.1.1. However, some studies may require that direct identifiers be stored for data matching or using some REDCap workflow automation functionality (i.e., Survey Module, Twilio, etc). When this is the case, appropriate approval and consent must be obtained. The following terms apply to users who are approved and will be using direct identifiers in their project:

2.1.2. Only include the minimum number of direct identifiers required for the project.

2.1.3. For research projects that require ethics approval, only identifiers approved by the REB will be allowed in the REDCap project.

2.1.4. Unless consent is waived by REB, participants must be appropriately consented, and the consent form should include language describing how REDCap is being used in the project. [Review our boilerplate language for consent forms for more information.](#)

2.1.5. If consent is being obtained electronically through REDCap (E-Consent), please refer to our [E-Consent standard operating procedure.](#)

2.1.6. Direct identifier fields must be set as identifiers. This option is available within all REDCap fields.

2.1.7. Principal Investigator's (PI's), or their approved delegates, are responsible for ensuring user rights are assigned appropriately. Access to identifying information within projects and through data exports should be limited to only members of the research team who require access.

2.1.8. Identifying information is to be removed from the project once data collection is complete.

2.1.9. REDCap is available for use in quality improvement projects. These projects typically do not require REB approval/clearance. However, if a project is collecting identifiable healthcare information from one of our hospital partners, they must ensure they have the appropriate approval from their respective institution.

2.1.10. REDCap administrators will review production status requests for these projects with identifiers fields and ensuring that proper approvals have been obtained.

2.1.11. Please refer to the [WE-SPARK REDCap Privacy Policy](#) for more information on identifiers/identifiable healthcare information and REDCap usage. If you have any further questions, you can contact redcap@uwindsor.ca.

2.2. Sharing accounts is prohibited. You will not provide your login information to anyone.

2.3. You will not attempt to access any data or projects for which you do not have authorization.

2.4. You are required to maintain confidentiality when using REDCap.

3. REDCap Administration Access

3.1. Members of the WE-SPARK team or REDCap users from our partner institutions may be assigned REDCap Administrator Privileges to assist with day-to-day REDCap operations. Some REDCap Administrators are **REDCap Super Users.** REDCap Super Users are REDCap Administrators with **access to all projects, data with maximum user privileges, and managing user accounts.**

3.2. REDCap Super Users reserve the right to:

    3.2.1. Audit user accounts at anytime to determine if accounts are still active or require termination.

    3.2.2. Audit existing REDCap projects to ensure compliance with the Terms of Use and REB approvals where applicable.

    3.2.3. Notify REB of Record or WE-SPARK Partner institutional stakeholders of violations of the Terms of Use.

3.3. REDCap Super Users may review any projects during auditing, and thus have access to project data. It is the responsibility of the REDCap user to inform their research participants in the consent process that REDCap Super Users have access to their project data and may view this data during an audit.

3.4. REDCap users are advised to address this in their project Informed Consent Form's (ICF's). Review our boilerplate language for consent forms for more information.

4.   Responsibilities of the Principal Investigator (PI) and study teams when using REDCap

4.1. All REDCap projects are started in development mode. **For REB approved research projects collecting human participant data in REDCap, projects must enter production mode before collecting this data.** Please review our "[Moving to Production Status in REDCap](#)" Standard Operating Procedure for more information.

4.2. REDCap Super User(s) will request approval documents, review the REDCap project, and move to production status if appropriate.

4.3. All accounts requested will be reviewed by the REDCap administrator.

4.4. PIs will authorize the application for REDCap accounts for members of their current study team.

4.5. It is the responsibility of the PIs or their delegates to assign the appropriate user rights for their study staff on their REDCap project. WE-SPARK Health Institute, University of Windsor ITS and the Office of Research Ethics/REB are not responsible for assigning user roles or damages caused by improper user role assignment. PIs or their delegates can request assistance from the REDCap Administrator regarding user rights and role assignment.

4.6. PIs must ensure that their team members adhere to the Terms of Use.

4.7. WE-SPARK Health Institute will provide introductory training to REDCap for all users. It is the responsibility of the PIs or their delegates to ensure their study team is sufficiently trained for the requirements of their projects.

4.8. PIs must monitor project access regularly and remove user accounts that no longer require access to their projects. WE-SPARK Health Institute is not responsible for removing accounts.

4.9. PIs or their delegates are responsible for importing and exporting study data into and out of their REDCap projects. They are also responsible for deleting or archiving completed projects as per Tri-Council policies and the REB as it pertains to research data.

4.10. PIs are to contact the REDCap administrator at redcap@uwindsor.ca for any issues related to lost or accidently deleted data. The REDCap Administrator will work with University of Windsor ITS to recover lost or deleted data. It is best practice for PIs and their study team to save and download their projects regularly to avoid this. In some circumstances it will be impossible to recover lost or deleted data.

4.11. PIs or their delegates must inform the REDCap Administrator if an external auditor from a sponsor or another institution has requested access to data in REDCap.
4.12. If members of the study team are no longer with, WE-SPARK Health Institute or the partner institutions and do not require REDCap accounts any longer, it is up to the PI or their delegates to inform the REDCap Administrator.

4.13. Accounts that have been inactive for at least two years will be suspended. A suspended user can email redcap@uwindsor.ca to have their account reinstated provided that their PI approves

4.14. All accounts requested will be reviewed by the REDCap administrator.

4.15. Is will authorize the application for REDCap accounts for members of their current study team.

4.16. It is the responsibility of the PIs or their delegates to assign the appropriate user rights for their study staff on their REDCap project. WE-SPARK Health Institute, University of Windsor ITS and the Office of Research Ethics/REB are not responsible for assigning user roles or damages caused by improper user role assignment. PIs or their delegates can request assistance from the REDCap Administrator regarding user rights and role assignment.

4.17. PIs must ensure that their team members follow the Terms of Use.

4.18. WE-SPARK Health Institute will provide introductory training to REDCap for all users. It is the responsibility of the PIs or their delegates to ensure their study team is sufficiently trained for the requirements of their projects.

4.19. PIs must monitor project access regularly and remove user accounts that no longer require access to their projects. WE-SPARK Health Institute is not responsible for removing accounts.

4.20. PIs or their delegates are responsible for importing and exporting study data into and out of their REDCap projects. They are also responsible for deleting or archiving completed projects as per Tri-Council policies and the REB as it pertains to research data.

4.21. PIs are to contact the REDCap administrator at redcap@uwindsor.ca for any issues related to lost or accidently deleted data. The REDCap Administrator will work with University of Windsor ITS to recover lost or deleted data. It is best practice for PIs and their study team to save and download their projects regularly to avoid this. In some circumstances it will be impossible to recover lost or deleted data.

4.22. PIs or their delegates must inform the REDCap Administrator if an external auditor from a sponsor or another institution has requested access to data in REDCap.

4.23. If members of the study team are no longer with, WE-SPARK Health Institute or the partner institutions and do not require REDCap accounts any longer, it is up to the PI or their delegates to inform the REDCap Administrator.

4.24. Accounts that have been inactive for at least two years will be suspended. A suspended user can email redcap@uwindsor.ca to have their account reinstated provided that their PI approves.

If any of the above terms are violated, the user accounts associated with the violation will be suspended pending an appropriate investigation by the REDCap Administrator, the Office of Research Ethics/REB and/or University of Windsor ITS. There may be additional repercussions depending on the severity of the violation as determined by the REDCap Administrative bodies or other bodies of oversight.

University of Windsor Information Technology Services will take great effort in maintaining uptime, security, and data integrity. However, system failures, data breaches and non-recoverable loss of data are possible.

These terms of use may be modified over time. The REDCap Administrator will make it known when changes are made, and they will be available on the REDCap login page. It is your responsibility to review any changes and ensure that you are following them.

If you do not agree to the terms above, please discontinue your application for a REDCap account. If you have an account and do not agree with updated terms, you must discontinue your use of REDCap and contact the REDCap Administrator at redcap@uwindsor.ca immediately.

By continuing with the account creation process you are agreeing to abide by the terms and conditions listed in this document.

_____   _____

Applicant Signature   Date

_____   _____

REDCap Admin Signature   Date
(internal use only; do not sign here)

Date	Version No	Revision Type (minor edit, moderate revision, complete revision)	Reference Section(s)
08-June-2023	7.0	**Complete Revision:** 1. Structural Changes to Form. 2. Language revisions throughout form to ensure clarity. 3. Grammatical and typographical revisions throughout form. 4. Update to production status procedures	2. Confidentiality • Updated section 2.1 and subsections regarding moving projects to production status. All research projects involving human participants are now required to be in production status in order to enter participant data.
16-Feb-2022	6.0	**Complete Revision:** 5. Structural Changes to Form. 6. Language revisions throughout form to ensure clarity. 7. Grammatical and typographical revisions throughout form. 8. Addition of the Confidentiality Section. 9. Addition of the REDCap Administration Access.	1. General 2. Confidentiality 3. REDCap Administration Access 4. Responsibilities of the Principal Investigator (PI) and study teams when using REDCap

05-May-2021	5.0	**Complete Revision** Updated terms on storage of personal identifiers	1. General
01-Dec-2020	4.0	**Complete Revision:** Final Version of Terms of Use Established	N/A