

Research St. Joseph's – Hamilton (RSJ-H)		Pages 1 of 5	Number 051-RSJ-H
Policy Title REDCap™ Appropriate Use		Date 31 March 2022	
Supersedes 01 April 2014		Cross Reference	Issuing Authority RSJ-H Scientific Director
<input checked="" type="checkbox"/> Charlton Campus	<input checked="" type="checkbox"/> West 5th Campus	<input checked="" type="checkbox"/> King Campus	

Position responsible for developing and maintaining the policy: RSJ-H Scientific Director

1.0. PURPOSE

Provide guidance to those associated with RSJ-H who would like to use REDCap™ in the conduct of research related matters; including research, academic, and operational data collection. The purpose of this policy is to assist investigators, to protect patient privacy and confidentiality, to ensure that all data is collected within the bounds of the REDCap license (Appendix A) and institutional requirements.

2.0 SCOPE

REDCap (Research Electronic Data Capture) is a web-based software program created by Vanderbilt University and supported by the REDCap Consortium to facilitate research and data collection. Research St. Joseph's – Hamilton is a member of this consortium and is permitted to run a copy of the software on its server (an instance). RSJ-H can allow Affiliated Researchers and their Staff and collaborators access to the software provided that the REDCap licensing and Institutional requirements are met.

REDCap has an authorization matrix, allowing different members of the study team to have different levels of access (none, read-only or edit) to data entry forms, and access to project management and data export tools. There are provisions to restrict access to data export to allow export of de-identified data only.

REDCap enforces authorization granted to each user by providing and/or enabling certain functions, tabs, links and buttons according to granted privileges. REDCap includes a full audit trail, recording all operations on the data, including viewing and exporting. The audit log records operation, date and time, and the user performing the operation, permitting review of the audit trail as necessary. Additionally, REDCap can help to ensure data quality through use of Double Data Entry mode, forms and records locking and electronic signatures.

REDCap is third-party software. In no way does RSJ-H certify software integrity or take responsibility for the software or its operation. Unexpected behavior, data loss and failure may occur at any time and although RSJ-H will do its utmost to reduce the risk of such events it in no way certifies that they will not occur.

These Research St. Joseph's - Hamilton policies are **CONTROLLED** documents as are all management system files on the intranet. Any documents appearing in paper form are not controlled and should **ALWAYS** be checked against the intranet version (electronic version) prior to use.

3.0 DEFINITION OF TERMS

- 3.1 **PI / Principal Investigator** - An RSJH Affiliated Researcher responsible for the conduct of the research study, including assignment of the roles and authorizations to use specific forms and functions of REDCap to the members of the research team.
- 3.2 **Project Team Member** – PI, research assistants, nurses, project managers, data entry persons and other personnel granted access to REDCap projects.
- 3.3 **Project** - Database or survey implemented in REDCap. A set of data entry forms, schedules and other REDCap instruments pertaining to a specific study or research project.
- 3.4 **Development mode** - A state of the Project that allows authorized team members to add, modify or delete data entry forms and other elements of the study design. In the development mode, the database is temporary and is not backed up. No data is guaranteed to be preserved in the database in this mode.
- 3.5 **Production mode** - A state of the Project that allows authorized team members to add, modify or delete data. Any data entered in this mode will be protected by nightly back-ups for up to 30 days. Any modification to the data collection design in this mode will need to be approved by a REDCap Super User. The REDCap Super User offers as a service to review proposed changes before approval to ensure data integrity.
- 3.6 **REDCap System Admin** - RSJ-H personnel responsible for implementation and maintenance of REDCap software and servers (example: back-up, system upgrades, security patches).
- 3.7 **REDCap Super User** - RSJ-H personnel responsible for user education and management of projects (example: moving to production, approving changes when in production).
- 3.8 **Authentication** - A confirmation from the authoritative source (REDCap table based authentication) that the user credentials (user name and password) are valid. Additionally persons accessing REDCap from outside of the St. Joseph's Healthcare Hamilton network will be required to provide a second level of authentication (emailed code or Google Authenticator).
- 3.9 **Authorization** - A set of rights to access specific objects (forms, tabs, controls) in specific mode (read-only, read-write or edit, full data set, de-identified data set) granted to a user.

4.0 POLICY

Any authenticated user has a right to access REDCap, review public projects (e.g., demo databases) and request a new database or modify a database to which corresponding authorization is granted (e.g., their own). Currently, REDCap's table-based authentication serves as the sole authentication source. Any new user is strongly encouraged to review the online tutorials before attempting to create new projects.

For the duration of the REDCap project, it is the responsibility of the PI to:

1. Ensure the project has been approved through an RSJ-H authorized Research Ethics Board (REB), as required.
2. Ensure that if used as part of a multi-centre trial, the RSJ-H Affiliated Researcher must be the Lead PI of the study and RSJ-H or St. Joseph's Healthcare must be the primary, coordinating site for the study.
3. Work with RSJ-H Administration to ensure that all agreements are in place with any external site that will be entering data into the RSJ-H instance of REDCap before starting data collection.
4. Provide a list of Project Team Members who will have access to REDCap to RSJ-H Administration.
5. Submit amendments to REB, as necessary, to ensure continuing compliance with research protocols.
6. Build the REDCap project (entry forms) in such a way that it corresponds to the study design and provides proper data collection tools for all the data necessary for testing study hypothesis. . A consultation with the biostatistics unit is strongly recommended prior to project start to ensure that the data collected will meet these requirements.
7. Collect only minimally-necessary set of PHI data (protected health information), in addition to those required by study design or operational requirements, to positively identify study subject during data entry phase. Mark all PHI data fields as "Identifiers =Yes".
8. Collect only the data necessary for required outcome analysis as approved by REB. Assign and maintain the roles and authorizations for Project Team Members to use specific forms and functions (grant and restrict access via User Rights page).
9. Assign only Full Data Export rights for projects with PHI to those individuals trained to protect PHI and/or are using computers that meet the requirements for containing sensitive information.
10. Test the project (User Acceptance Testing) prior to requesting the project be moved to production mode, including data entry, review of project unique identifier, data export formats etc., to ensure the project design is appropriatevvvv During the development process, no data collection can take place.
11. Request project be moved to production, once approved data collection can commence.
12. Request design changes via the user interface during production mode.
13. vOnce data collection is complete, move the project to "Analysis/Cleanup" status. This will "freeze" that database so now new data can be entered.

14. Once analysis is complete, move the project to “Complete” status or delete the project.
15. Manage access to the project to ensure compliance with the Personal Health Information Protection Act (PHIPA) and all other applicable provincial and federal statutes and regulations protecting patient privacy and confidentiality (ensure that each user is granted the minimum amount of access needed to perform his/her duties).

REDCap Super Users reserve the following rights:

1. Ability to notify and report to REB and/or Department of Risk, Legal & Privacy on the activity and authorized users of all human research projects. The report will allow HiREB to monitor protocol compliance.
2. Grant access to REB / Department of Risk, Legal & Privacy or other authorized auditors (such as Health Canada or auditors authorized by RSJ-H) upon request to audit projects.
3. Record and track REB approved research protocols utilizing REDCap in a database, including the name of the PI, the REB protocol number, the date of project creation, and date of project move to production.
4. Suspend projects that are deemed to be in violation of the REDCap license or institutional requirements.
5. Promptly remove or disable user access for persons and entities that no longer need access to REDCap.
6. Create "revision reports" within the project while reviewing requested changes. Reports will be deleted immediately after review.
7. Review and assign protections to data fields with Personal Health Information by indicating “Identifiers=Yes” when moving the project to production and assign protections to identifiers with PHI.

Appendix A

REDCap License Terms

REDCap Non-Profit End-User License Agreement

This non-profit end-user license agreement ("Agreement") is made by and between Vanderbilt University ("Vanderbilt"), a not-for-profit corporation duly organized and existing under the laws of Tennessee and having offices at 1207 17th Avenue South, Suite 105, Nashville, Tennessee 37212, and your organization through you (the "Licensee"). Both Vanderbilt and Licensee are referred to as the "Parties" or, individually, as a "Party."

RECITALS

Vanderbilt is the owner of all rights, title and interest in and to the Research Electronic Data Capture Software also known as "REDCap," and has the right to grant licenses for use of the Software (as defined in Section 1.5 below). Licensee desires to obtain a license to use said Software for Non-Commercial Research Purposes (as defined in Section 1.6 below) only.

Vanderbilt, Licensee, and other third party non-commercial licensees of the Software (individually, a "Consortium Member" and, collectively, the "Consortium Members", as further defined in Sections 1.1 and 1.2 below), desire to use the Software and create Derivative Works of same either collaboratively or independently.

1. DEFINITIONS

For the purposes of this Agreement, the following terms, when appearing with an initial capital letter, shall have the meaning designated below:

1.1 "Consortium" means the group of REDCap institutional partners from CTSA, GCRC, RCMI and other institutions in several countries as further defined and described on the REDCap website (<http://projectredcap.org/>).

1.2 "Consortium Member" is an institutional partner of the Consortium.

1.3 "Derivative Works" means any derivative works (as defined by the [U.S. Copyright Laws at 17 U.S.C. §101](#)) of REDCap, regardless of author.

1.4 "Permitted Users" means Licensee's employees who are expressly authorized in writing by Licensee to use the Software in conformity with the terms of this Agreement.

1.5 "Software" means the Research Electronic Data Capture Software (also referred to herein as "REDCap"), the REDCap source code, and any Derivative Works created by Vanderbilt, Licensee or other Consortium Members.

1.6 "Non-Commercial Research Purposes" means for internal research, internal operations and internal educational purposes only, which research, operational or educational uses are to be conducted by Licensee in a manner consistent with its tax-exempt status and may include research funded by commercial (for profit) organizations, but shall not include use of the Software as the basis for providing a contract or other services to any entity.

2. GRANT OF LICENSE BY VANDERBILT

These Research St. Joseph's - Hamilton policies are **CONTROLLED** documents as are all management system files on the intranet. Any documents appearing in paper form are not controlled and should **ALWAYS** be checked against the intranet version (electronic version) prior to use.

2.1 (a) Subject to the terms and conditions of this Agreement, Vanderbilt hereby grants to Licensee, and Licensee accepts from Vanderbilt, a non-exclusive license for Licensee's Permitted Users solely to use the Software and make Derivative Works of same for Licensee's own Non-Commercial Research Purposes only. LICENSEE UNDERSTANDS AND AGREES THAT NEITHER THE SOFTWARE NOR ANY DERIVATIVE WORKS MAY BE DISTRIBUTED TO OR SHARED WITH ANY THIRD PARTY FOR ANY PURPOSE.

(b) The Software may only be installed (i) on servers and computers owned by Licensee or (ii) on web-based or "cloud" servers where the third party hosting company has been hired by Licensee and provided that the third party hosting company has no access whatsoever to the Software. Licensee is responsible for ensuring the web-hosting service is able to properly maintain in confidence the Software (including all REDCap source code) and "Protected Health Information" in conformity with HIPAA (as defined below). Furthermore, if the Software is installed on portable devices, Licensee is responsible for ensuring that the Software source code shall be encrypted to protect the Software from unauthorized use or disclosure.

(c) Notwithstanding the foregoing, Licensee may allow limited access to the Software by a third party research collaborator ("Collaborator") to permit entry of data by the Collaborator as part of a multi-site data collection effort related to joint research in which the Collaborator is actively and materially involved. Such Collaborator shall not be permitted any other access to or use of the Software.

(d) Licensee acknowledges that when new version are made available, Vanderbilt has no obligation to support any past version, and past versions may no longer be accessible or otherwise available for use.

2.2 Upon execution of this Agreement, Vanderbilt shall deliver to Licensee the current version of the Software and may, from time-to-time, make new versions of the Software available as Vanderbilt determines is practicable. Vanderbilt shall determine which, if any, Derivative Works shall be distributed to Consortium Members and the terms under which such Derivative Works shall be distributed.

2.3 Licensee acknowledges that no training, support, hosting, or other services from Vanderbilt will be provided under this Agreement.

2.4 Vanderbilt reserves all rights in and to the Software not specifically conveyed pursuant to this Agreement. Vanderbilt also reserves the right to publish a selected list of Licensees of the Software and list of Consortium Members.

2.5 Vanderbilt shall have the right, with written notice to Licensee, to amend, modify or revise any term or terms of this Agreement at any time in its sole and absolute discretion. Such amendments, modifications or revisions shall be posted to the REDCap administrative mailing list (redcaplicense@list.vanderbilt.edu.) To subscribe to the administrative mailing list, Licensee must send an email to LISTSERV@list.vanderbilt.edu with the text "subscribe redcaplicense" in the message body. Within thirty (30) calendar days of the date such written notice is posted to redcaplicense@list.vanderbilt.edu, Licensee shall have the right to terminate this Agreement, thereby rejecting the terms of such amendment or revision. If Licensee so elects to terminate this Agreement, it shall promptly discontinue all use of the Software, remove all copies of the Software from Licensee's computers and servers (including from the computers of any third party hosting company), and return to Vanderbilt all copies of the Software in Licensee's possession or control and certify in writing to Vanderbilt that it has fully complied with these requirements. Should Licensee not provide notice of termination (including via non-response) within such thirty (30) day period, such amendments, revisions and modifications shall remain binding and enforceable on Licensee without the need for either Party to take any further action or make any further agreement or amendment.

2.6 Vanderbilt shall have the right to terminate this Agreement, at its discretion, for any reason upon providing Licensee with ninety (90) days advance notice. However, in the event that Vanderbilt determines that an incurable breach of this Agreement by Licensee has occurred, said advance notice period shall be reduced to thirty (30) days; and in the event exigent circumstances exist, Vanderbilt shall have the right to terminate this Agreement immediately with notice.

2.7 Eligible Licensees. This REDCap license is intended to provide access and use of the REDCap Software to (i) not-for-profit (including governmental and military) institutions and (ii) other non-commercial entities and non-commercial organizations in countries that do not recognize not-for-profit status. In the event that Vanderbilt determines, at any time and in its sole discretion, that a Licensee does not meet its requirements, Vanderbilt shall have the right to terminate this Agreement upon ten (10) days written notice. If the Licensee is in breach of its representations set forth in Sections 6.2 or 6.8 hereinbelow, this Agreement shall be hereby and immediately rendered null, void and without effect.

2.8 Payment for License. Under this Agreement, REDCap is currently provided at no cost to Licensee.

3. GRANT OF LICENSE BY LICENSEE

3.1 Subject to the terms and conditions of the Agreement, and to the extent not already covered herein, Licensee hereby grants to Vanderbilt, and Vanderbilt accepts from Licensee, a fully-paid, transferrable and sublicensable exclusive license to use reproduce, prepare derivative works from, and distribute copies of Derivative Works created by Licensee. Derivative Works include, but are not limited to, customizations of and extensions to the REDCap source code, but exclude Licensee's data or data collection forms. Vanderbilt and Consortium Members shall have the right to use and to create further Derivative Works based on Derivative Works created by Licensee, subject to the terms of this Agreement. However, no Consortium Members (including Licensee), with the exception of Vanderbilt, shall have any distribution or commercialization rights with respect to the Software.

3.2 Vanderbilt shall coordinate all publications related to the Software itself, including those describing its methodologies, functionality, and/or capabilities to support research related to electronic data capture. As such, Vanderbilt shall have the right to review, edit and approve publications created by Consortium Members which discuss the Software and its methodologies, functionality, and/or capabilities.

3.3 In addition to Licensee's right to terminate this Agreement as set forth in Section 2.5 above, Licensee shall have the right to terminate this Agreement at its discretion for any reason upon providing Vanderbilt with ninety (90) days advance written notice. Upon such termination, Licensee shall promptly discontinue all use of the Software, remove all copies of the Software from Licensee's computers and servers, and return to Vanderbilt all copies of Software in Licensee's possession or control and certify in writing to Vanderbilt that it has fully complied with these requirements.

4. INTELLECTUAL PROPERTY

4.1 Ownership of all rights, including the copyright in the Software, shall at all times remain with Vanderbilt.

4.2 Licensee agrees to reproduce, in accordance with the requirements of U.S. Copyright statutes, the copyright notice of Vanderbilt on all embodiments of the Software. The form of such markings shall be "Copyright 2006-2013 Vanderbilt University. All Rights Reserved." The notice shall be affixed to all copies or portions thereof in such manner and location as to give reasonable notice of Vanderbilt's claim of copyright. Licensee shall at all times hereafter protect the Software from unauthorized transfer or duplication using measures at least as

effective as those used by Licensee in protecting its own intellectual property, but in no event less than a reasonable standard of care.

5. WARRANTY

5.1 VANDERBILT MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR VALIDITY OF THE SOFTWARE OR THE COPYRIGHTS THERETO. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY VANDERBILT THAT THE PRACTICE OR USE BY LICENSEE OF THE SOFTWARE DOES NOT AND SHALL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY. FURTHERMORE, VANDERBILT EXTENDS NO WARRANTIES OF ANY KIND THAT THE SOFTWARE SHALL OPERATE IN CONFORMITY WITH ANY USER MANUALS OR OTHER LITERATURE THAT MAY BE DISTRIBUTED FROM TIME TO TIME.

5.2 LICENSEE MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND VALIDITY OF LICENSEE DERIVATIVE WORKS AND COPYRIGHTS THERETO.

5.3 Neither Vanderbilt nor any of its officers, employees, agents, contractors, successors or assigns shall be liable to the Licensee for any damages or losses of any kind (whether from special, direct, indirect, or consequential circumstances) arising out of its performance or non-performance under this Agreement or use of the Software.

6. MISCELLANEOUS AND GENERAL PROVISIONS

6.1 This Agreement shall be construed, governed, interpreted and applied in accordance with the federal laws of the United States and the State laws of Tennessee, except where prohibited by law. The Parties agree to the exclusive jurisdiction of the courts of competent jurisdiction in Davidson County, Tennessee or the United States District Court for the Middle District of Tennessee, except where prohibited by law.

6.2 Licensee shall comply with all export control laws and regulations of the United States, including the Export Administration Regulations ("EAR") (15 C.F.R. §730-744), the International Traffic in Arms Regulations ("ITAR") (22 C.F.R. § 120-130), and the economic sanctions programs administered by the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC") (as set forth in 31 C.F.R. §500-598 and certain executive orders,) and shall not export or re-export the Software in violation of any such laws or regulations, or without all necessary approvals. Diversion of the Software contrary to U.S. law is prohibited. The parties acknowledge that neither the Software nor the underlying information or technology may be downloaded or otherwise exported or re-exported (A) into Cuba, Iran, North Korea, Sudan, Syria, the Crimea region of the Ukraine or any other country or territory subject to U.S. trade sanctions applicable to the Software or (B) to anyone on (i) the U.S. Treasury Department's list of Specially Designated Nationals and Blocked Persons, (ii) the U.S. Commerce Department's Denied Persons List, Entity List or Unverified List or (iii) the Non-proliferation Sanctions List. Licensee agrees to the foregoing and represents and warrants that it complies with these conditions, is in good standing and eligible to receive the license granted hereunder, and shall continue to operate in compliance with these representations.

6.3 Vanderbilt and Licensee are not partners, joint ventures or agents of the other under this Agreement, and nothing shall be construed as causing them to be such. Neither Party shall have authority to act in the other's name, nor act for the other's benefit, except as is expressly provided for in this Agreement.

These Research St. Joseph's - Hamilton policies are **CONTROLLED** documents as are all management system files on the intranet. Any documents appearing in paper form are not controlled and should **ALWAYS** be checked against the intranet version (electronic version) prior to use.

6.4 Neither Party shall use the other Party's name or any adaptation of it in any advertising, promotional or sales literature without the prior written consent of the other Party except as provided in this Agreement.

6.5 Without the prior written approval of Vanderbilt, Licensee may neither assign its rights nor delegate its duties under this Agreement to any other party. Vanderbilt shall have the right to assign its rights and delegate its duties under this Agreement, however. This Agreement shall be binding upon the successors and legal representatives of the Licensee.

6.6 In the event that any provision of this Agreement shall be held to be unconstitutional, invalid, illegal, or unenforceable for any reason, the remainder of this Agreement shall be interpreted as if such unconstitutional, invalid, illegal or unenforceable provisions were not contained herein. If necessary, in Vanderbilt's sole and absolute discretion, Vanderbilt shall modify such provision held to be unconstitutional, invalid, illegal, or unenforceable. The failure of one Party to assert a right hereunder shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party.

6.7 This Agreement constitutes the entire understanding between the Parties. Neither Party shall be obligated by any condition or representation other than those expressly stated in this Agreement, as amended.

6.8 Subject to the provisions of Section 2.7 hereinabove, the effective date of this Agreement is the date on which Licensee affirmatively accepts this Agreement by selecting "I Agree" below. Upon Licensee affirmatively accepting this Agreement by selecting "I Agree" below, Vanderbilt shall conduct an export control evaluation in conformity with the provisions of Section 6.2, applicable law and Vanderbilt policy, and otherwise verify that License qualifies as an Eligible License (as defined in Section 2.7 above).

6.9 Sections 2.4, 2.5, 3.1, 3.2, 4.1, 4.2, 6.2, 6.7, 6.8, 7.1, and 7.4 of this Agreement shall survive termination.

7. CONFIDENTIAL INFORMATION

As used herein, "Confidential Information" shall mean any and all technical and non-technical information provided by Vanderbilt to Licensee that is not generally available to the public. Confidential Information shall include, but is not limited to, patent applications, trade secrets proprietary information, ideas, techniques, sketches, drawings, manuals, works of authorship, models, inventions, know-how, processes, apparatuses, equipment, algorithms, software programs, software source documents, and formulae related to the current, future, and proposed products and services of Vanderbilt, information concerning research, experimental work, development, design details and specifications, engineering, financial information and forecasts, procurement requirements, purchasing, manufacturing, customer lists, investors, employees, business and contractual relationships, business forecasts, and information that Vanderbilt provides regarding third parties. In the event Confidential Information is disclosed to or otherwise obtained by Licensee, the following terms shall apply:

7.1 Licensee shall treat such Confidential Information as confidential and use the same degree of care as it employs in the protection of its own confidential information, but in no event less than a reasonable degree of care.

7.2 Licensee will restrict its use of the Confidential Information to the uses related to and consistent with its activities under this Agreement, and shall disclose Confidential Information only to those of its employees having a need-to-know to further the purposes of this Agreement, and provided that such employee agrees to comply with the terms of this Agreement.

7.3 This Agreement imposes no obligation upon Licensee with respect to Confidential Information that Licensee can establish, with clear and convincing documentary evidence:

These Research St. Joseph's - Hamilton policies are **CONTROLLED** documents as are all management system files on the intranet. Any documents appearing in paper form are not controlled and should **ALWAYS** be checked against the intranet version (electronic version) prior to use.

- (a) was in Licensee's possession before receipt from Vanderbilt;
- (b) is or becomes available to the public through no fault of Licensee;
- (c) is received in good faith by Licensee from a third party and is not subject to an obligation of confidentiality owed to the third party;
- (d) is independently developed by Licensee without reference to Confidential Information received hereunder;
or
- (e) is required to be disclosed by law.

7.4 Nothing in this Agreement shall in any way limit the ability of the Parties to comply with applicable laws and regulations requiring disclosures by public bodies. The Parties acknowledge that any responses, materials, correspondence or documents provided to the University are subject to all applicable state and federal Freedom of Information Act requirements ("Requirements") and that disclosures mandated by the Requirements may be released to third parties in compliance with such Requirements and such release shall not constitute a breach of this Agreement.

7.5 In no event shall Vanderbilt or Licensee disclose to the other any Protected Health Information ("PHI") as defined in the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. §1320d ("HIPAA"), and further in the Health Information Technology Act of 2009, as codified at 42 U.S.C.A. prec. § 17901 ("HITECH Act"). Each Party warrants that it will comply with (i) for Licensees headquartered in the U.S. or otherwise subject to U.S. law, both HIPAA and the HITECH Act, or (ii) for other Licensees, equivalent protected health information laws, rules and regulations to which they are subject in their jurisdiction, in connection with their respective performance under this Agreement. The Parties will each cooperate with the respective privacy officials and other compliance officers of the other Party as necessary for both parties to comply with all applicable regulations and will sign any documents that are reasonably necessary to maintain compliance with HIPAA and the HITECH Act in the event that it is decided the parties will share PHI in order to further the purposes of this Agreement or otherwise.

NOTICES

Any formal notice or other communication provided for in this Agreement shall be in writing and addressed to the Party.

Notices to Vanderbilt shall be sent to: Center for Technology Transfer and Commercialization
1207 17th Avenue South, Suite 105
Nashville, Tennessee 37212 USA
Attn: Assistant Vice Chancellor
Email: cttc@vanderbilt.edu (subject line: "REDCap")

Notices to Licensee shall be sent to the "Administrative Contact" indicated when Licensee applied for this license.

Such notice or other communication to Licensee shall be sent by (i) first-class U.S. Mail or express courier to the Party's street address, (ii) by facsimile or (iii) by email as indicated herein. Routine correspondence between the Parties may be made by email to the email address.

