

LSU Health New Orleans SPH Epi Data Center REDCap Project Owner Agreement

Project Owner Name: _____

Project Name: _____

Principle Investigator (if applicable): _____

School: _____ Department: _____

Phone: _____ Email: _____

IRB # (for human studies): _____ IACUC# (for animal studies): _____

Research Electronic Data Capture (REDCap) is a secure, web-based electronic data capture tool administered by the LSU Health New Orleans School of Public Health Epidemiology Data Center (EDC). REDCap was developed by a multi-institutional consortium initiated at Vanderbilt University. For more information please visit: <http://sph.lsuohsc.edu/redcap>

For the purposes of this REDCap Project Owner Agreement, a project owner is defined as the single person who will liaise with the EDC for REDCap access. This includes requesting: a REDCap project to be initiated, assistance while designing a project, and permissions for adding external users to the project. For the purposes of this REDCap Project Owner Agreement, a user is defined as any person who will be given REDCap user rights within the project.

If the REDCap project is being used for a research study, it is the responsibility of the Project Owner to inform the Principal Investigator of all the terms of this agreement.

In signing this agreement, the project owner is agreeing to the following:

1. To disclose, receive, transmit, maintain or create data consistent with the electronic data collection policies of LSU Health New Orleans, including but not limited to [CM-42](#).
2. If the project for which REDCap will be used involves human subjects research (per the U.S. Department of Health and Human Services (DHHS) Code of Federal Regulations definition¹), it must be APPROVED by the Institutional Review Board (IRB) before the project is moved to production and real study data collection can commence. If the project is a multi-site study, the project owner attests that appropriate IRB and regulatory approvals have been obtained prior to

¹ <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102>

collecting real study data and requesting access for the additional site(s). Additionally, the project owner will provide EDC with the approved protocol date and IRB number.

- a. If IRB Approval is not required for your study, please initial here: _____
3. The project owner understands that the collection of research data, including Protected Health Information (PHI; per the HIPAA Security Rule² and the HIPAA Privacy Rule³), requires that the project database be hosted by the LSU Health New Orleans Department of Information Technology behind their firewall in conjunction with the EDC.
4. To collect such data according to the Privacy Regulations and the Security Regulations under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations and guidance, all as amended from time to time (“HIPAA”) and the Health Information Technology for Economic and Clinical Health Act, as incorporated in the American Recovery and Reinvestment Act of 2009, and its implementing regulations and guidance issued by the Secretary, all as amended from time to time (“HITECH Act”); and to abide by all guidelines provided by the IRB.
5. To disclose personal information or private health information (PHI) only to those individuals who have a need to know such information in performance of their work and who have been trained according to and are in compliance with the guidelines set for by LSU Health New Orleans or as otherwise required by law.
6. The project owner is responsible for securing data downloaded from REDCap to a device (ex: computer, memory stick). If downloading PHI, the user must be trained in how to secure PHI. The project owner also is responsible for securely transferring data outside of the REDCap system. It is recommended that data be de-identified using the identifier flag in the system before being sent.
7. If the project for which REDCap will be used involves animal subjects, it must be APPROVED by the Institutional Animal Care and Use Committee (IACUC) (per the U.S. DHHS NIH Office of Lab Animal Welfare policy³) before the project is moved to production and data collection can commence. If the project is a multi-site study, the project owner attests that appropriate IACUC and regulatory approvals have been obtained prior to collecting data and requesting access for the additional site(s).
 - a. If IACUC Approval is not required for your study, please initial here: _____
8. The project owner understands that REDCap login credentials are the same as their LSUHSC-NO username and password. Neither project owners nor users will share their login credentials with others. All non- LSU Health New Orleans employees must obtain login credentials from the EDC to access REDCap and must meet all the same requirements described herein.
9. The project owner understands that the REDCap project will be actively maintained per the timeframe in the approved IRB protocol, or another timeframe agreed upon by all parties prior

² <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html>

³ <http://dhhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html>

to study initiation. The REDCap project will then be archived for an indefinite period of time. Once archived, the data will remain in the database (unless requested and justified by the project owner to be deleted permanently) and the study can be re-opened as necessary with the appropriate approvals.

10. The project owner understands that EDC staff or affiliated personnel will be responsible for:
 - a. Adding external LSU Health New Orleans users at the request of an LSU Health sponsor to the REDCap system if needed.
 - b. Approving and implementing any changes to a project once it is in production status. See LSU Health New Orleans SPH EDC REDCap Appropriate Use Policy for further information.
 - c. Approving API token requests.
11. The project owner is responsible for adding and assigning users with the appropriate access rights to the project.
12. The project owner is responsible for moving the project to production before collecting real study data.
13. Any publications resulting from the use of REDCap to collect and manage data must include the following REDCap citation:
Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr; 42(2):377-81.
14. The project owner understands that s/he is responsible for sharing and enforcing this Project Owner Agreement with any other REDCap project users in order to ensure all users are following LSU Health New Orleans and EDC rules and policies.
15. The project owner has read, fully understands and agrees to all portions of the LSU Health New Orleans SPH EDC REDCap Appropriate Use Policy.
16. If the project owner elects to design the REDCap Project without the support of the EDC staff and services, the project owner assumes all liability for the project's functionality.
17. It is the responsibility of the project owner to notify the EDC if a new project owner should be named to the project. All responsibilities and agreements herein are automatically transferred to the new project owner.
18. Unless otherwise stated, the named Principal Investigator of the project will be granted all the same user rights as the project owner.

Project Owner Signature: _____ Date: _____