

## REDCap and REDCap Survey User Agreement

Name: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

Institution: \_\_\_\_\_ Department: \_\_\_\_\_

Study Title: \_\_\_\_\_

Phone Number: \_\_\_\_\_

(FOR EXTERNAL USERS ONLY) Optimal Time You Can Be Contacted to obtain login

information): \_\_\_\_\_

Machine Platform: Mac / Windows / Linux / Other: \_\_\_\_\_

Cost Center/Grant # (if applicable): \_\_\_\_\_

Research Electronic Data Capture (REDCap) and REDCap Survey (furthered referred to as **REDCap**) are electronic data capture tools (owned by Vanderbilt University) and is provided by the Research Information Solutions and Innovation (RISI) within The Research Institute of Nationwide Children's Hospital.

In signing this agreement, the user is agreeing to the following:

1. 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 definition<sup>1</sup>), it has been submitted to the Institutional Review Board (IRB) for review or exemption and has been APPROVED before the project is moved to production and data collection can commence.
2. The user understands that the collection of Protected Health Information (PHI; per the HIPAA Privacy Rule<sup>2</sup>) requires that project database be hosted by the Nationwide Children's Research Institute Information Technology Department behind their firewall.
3. The user understands that PHI cannot be shared with any external party without a Materials Data Transfer Agreement (MDTA) or contract in place.
4. The user understands that REDCap login credentials are the same as their NCH username and password. In some cases, research accounts are still needed for NCH employees due to current network domain configuration. All non-NCH employees must obtain NCH login credentials to access REDCap, the user understands and agrees that their NCH login may only be used for purposes of the project referenced in this Agreement.
5. Users will not share their login credentials with other study personnel working on the project. Login credentials are easily obtained through the NCH Help Desk and can be expired for temporary employees. The user must immediately notify a REDCap administrator if they notice suspicious activity with their account or if they have been locked out.
6. Access to REDCap projects is dependent on the submission of a REDCap User's Rights Application, which defines all users, their project role and their access to specific aspects of REDCap functionality. If the project is using REDCap to collect PHI, the application must identify who has access to this information. This application must be submitted by the project owner, and must include

information for all study personnel either entering or accessing data stored with REDCap.

7. The user understands that the REDCap project will be actively maintained per the timeframe described in the user's approved IRB protocol, or other timeframe agreed upon by all parties prior to study initiation. The REDCap project will be archived after this time. Once archived, the data will remain in the database and the study can be re-opened as necessary with the appropriate approvals. The user understands that any data exported from REDCap that contains PHI needs to be encrypted or put on an encrypted device.
8. The user understands that a REDCap administrator will be responsible for:
  - a. Adding all new users to REDCap and assigning access rights per the submitted user matrix
  - b. Approve and migrate all new projects into production
  - c. Audit user access and data collection annually based on date of Production.
9. The user understands that the Principal Investigator of the study will be responsible for (all annual dates are based on the date the project went into Production):
  - a. An annual review of system activity within the database
  - b. An annual review of the users who have access to the database
  - c. Providing RISI with documentation of IRB approval annually.
10. The user understands that additional requirements are needed to make a REDCap database compliant with part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11). If data related to an IND is collected in this database it is the user's responsibility to inform RISI.
11. The user has read and agrees to comply with Nationwide Children's Technology Acceptable Use Policy, ADMIN XIV-6.
12. Any publications resulting from the user of REDCap to collect and manage data should include the following CTSA acknowledgement:

*The project described was supported by Award Number UL1RR025755 from the National Center For Research Resources. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center For Research Resources or the National Institutes of Health.*
13. Any publications resulting from the user of REDCap to collect and manage data should 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 user understands that any violations of this agreement could result in the termination of REDCap privileges.

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Printed Name

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Signature

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Date

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

<sup>2</sup> <http://dhhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html>