

## REDCap Survey & Questionnaire End---User Agreement

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

Marshall Health/Marshall University email Address: \_\_\_\_\_

Department/College: \_\_\_\_\_

Research Electronic Data Capture (REDCap) and REDCap Survey (furthered referred to as **REDCap**) are electronic data capture tools provided by the Clinical Informatics Core within The Appalachian Clinical & Translational Science Institute (ACTSI) through a license from the Vanderbilt University REDCap group. As such, REDCap can only be used to support the research program of the authorized user, the user's supervisor, or the research administration at Marshall Health and Marshall University. In signing this agreement, the user is agreeing to the following:

1. If the REDCap project involves *human subjects research* (per the U.S. Department of Health and Human Services [DHHS] Code of Federal Regulations definition1), 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. Additionally, the project owner will provide the ACTSI with the approved protocol, as well as all related consent/assent forms, letter(s) of approval (including initial approval and any continuing reviews and/or amendments) and/or HIPAA Research Authorization Form (as appropriate).
2. The user understands that the collection of Protected Health Information (PHI; per the HIPAA Privacy Rule2) requires that project database be hosted by the ACTSI Clinical Informatics Department behind the Marshall University firewall, and that access outside of the Marshall Health and Marshall University and specific Marshall Health domains will require the use of a secure login method as explained below.
3. Human subject research questionnaires are created under the REDCap **Secure**, internal website. This website exists under the Marshall Health firewall with access restricted to a login prompt under the Marshall Health network, <https://redcaps.marshall.edu/redcap/>, or by using remote access to securely log into the Marshall Health network. Outside access is located at <https://physicianportal.marshall.edu> and requires a username and password, which is provided by ACTSI.
4. User understands that IRB approval letter, protocol has to be submitted to get access to the **secure** site. The title of the IRB should match the REDCap study title
5. Administrative and other non-human subject research surveys are created under the REDCap **global** website and can be accessed through email or, using a link embedded on any Marshall Health, Marshall University, or other approved web sites. No login is required to complete the administrative or non-human survey and the location of the online survey link is generated during the creation of the survey. Access to develop the surveys is through <https://redcap.marshall.edu/redcap> and requires a username and password, which is provided by Division of Clinical Informatics, ACTSI.
6. REDCap login credentials are provided by contacting the Clinical Informatics Core. Non- Marshall Health and University REDCap users, sponsored by an authorized Marshall Health researcher, will be provided guest login accounts.
7. Users will not share their login credentials with other study personnel working on the project. Login credentials are easily obtained by contacting the ACTSI Research Informatics Core.
8. The user understands that REDCap login credentials are provided by Appalachian Clinical & Translational Science Institute specifically for approved research activity and can be revoked at any time.

1. <http://www.hhs.gov/ohrp/humansubjects/guidance/>
2. <http://dhhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html>
  
9. If you are coordinating a multi-center study where the PI is located at Marshall Health or Marshall University, you are well within your rights to use REDCap to support the study. On the other hand, if you want to use your local REDCap installation to support researchers at another institution (for single- or multi-center studies) where you do not have a local researcher involved in the study, this can be a violation of the REDCap licensing agreement. Offering external research teams the use of a REDCap installation on a fee-for-service basis (or even gratis) is strictly forbidden under the licensing model.
  
10. Access to REDCap projects is dependent on the submission of a user rights matrix, 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 data access worksheet must identify who has access to this information. This worksheet must be submitted by the project owner, and must include information for all study personnel either entering or accessing data stored with REDCap.
  
11. 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 (unless requested by the user to be deleted permanently) and the study can be reopened as necessary with the appropriate approvals.  
*The user understands that ACTSI Research Informatics Services (RIS) Core will be responsible for adding all new users to REDCap and assigning access rights per the submitted user matrix*
  
12. Any publications resulting from the user of REDCap to collect and manage data should include the following ACTSI 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.*

Signature:

Date:

---

---