



UC Davis REDCap Project Level Agreement

Name of PI: _____

Department: _____ Project End Date: _____

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

Research Electronic Data Capture (**REDCap**) is a data management tool administered by the Biomedical Informatics Program of the Clinical and Translational Science Center (**CTSC**) and maintained by **Research IT** at UC Davis Health (**UCDH**).

For more information please visit:

<https://health.ucdavis.edu/ctsc/area/informatics/ElectronicDataCapture.html>

In signing this agreement, the project owner 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 definition¹), it must be APPROVED by the Institutional Review Board (IRB) 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 IRB and regulatory approvals have been obtained prior to collecting data and requesting access for the additional site(s).
 - a. If IRB Approval is not required for your study, please initial here: _____
2. The project owner understands that the collection of research data, including Protected Health Information (PHI; per the HIPAA Security Rule²), requires that the project database be hosted by the UCDH Information Technology Department.
3. 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: _____
4. The project owner understands that each study team member must submit a Service Request to obtain access to REDCap.

For UCDH Users, please follow the instructions found on this link:

<https://health.ucdavis.edu/ctsc/area/informatics/documents/ServiceNow-Request-for REDCap-database.pdf>

For non-UCDHS Users, the sponsor will need to create Kerberos login by completing the [UC Davis Temporary Affiliate Form](#).

5. Access to REDCap projects is dependent on the completion of a user permissions listing, which defines all study team members, data access groups, project roles and access to specific aspects of REDCap functionality. The user permissions listing must identify who has access to any PHI that may be collected. This listing must be completed by the project owner and must include information for all study team members interacting with REDCap. This listing can be resubmitted as needed.

https://health.ucdavis.edu/ctsc/area/informatics/documents/roles_and_permissions_matrix-190806.xlsx

6. The project owner must submit a [CTSC Application for Resource Use](#) and be APPROVED before the project is moved to production and data collection can commence. Additionally, the project owner will provide the CTSC with any additional information required for the CTSA Annual Report to the National Institutes of Health (NIH).
7. 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 to study initiation. The REDCap project will then be archived for an indefinite period of time.
8. The project owner ensures that the data dictionary they develop supports the reliability and validity of the project. It is highly recommended that the project owner consult with a biostatistician, if they already have not.
9. The project owner understands that CTSC staff or affiliated personnel will be responsible for:
 - a. Assigning access rights per the submitted user permissions listing
 - b. Approving and migrating all new projects into production
 - c. Approving and implementing any changes to a production database
10. Any publications resulting from the use of REDCap to collect and manage data should include the following CTSA acknowledgement:

"The project described was supported by the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), through grant UL1 TR001860."

11. Any publications resulting from the use 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.

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

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

3 <https://olaw.nih.gov/resources/tutorial/>

Signature:

Date: