**FAQs**

# Validation

*Validated by the FDA?
Who did the validation?
Who was the vendor partner?
Will we have access to the validation package?*

The University of Pittsburgh’s 21 CFR Part 11 Verified REDCap instance was validated by Pitt in collaboration with our Vendor partner. For additional questions regarding Part 11 validation, please contact the office of the Vice Chancellor and Deputy Chief Information Officer, Health Sciences.

# Billing

*Will HSIT bill to the study to maintain validation?*

Health Sciences IT is planning to begin charging nominal fees for use of the 21 CFR Part 11 Verified REDCap instance starting in FY25. The pricing structure is still being solidified.

# Other Systems

*Sounds like WDX (OAC Western Psych) – is WDX validated?*

We cannot speak to if WDX is validated or not. We are not familiar with the system. To the best of our knowledge, the REDCap system is the only validated system in the Pitt Ecosystem.

*(*[*https://www.oac.pitt.edu/services/webdataxpress*](https://www.oac.pitt.edu/services/webdataxpress) *- Please contact the department with any questions.)*

# Other Compliance Regulations

*Are the forms CDASH compliant?*

REDCap, by default, is not Clinical Data Acquisition Standards Harmonization (CDASH) compliant. However, the Clinical Data Interchange Standards Consortium (CDISC) has made a number of CDASH compliant CRFs available for use through the REDCap Shared Library. Contact the HSIT REDCap team for more information.

# UPMC

*Is this REDCap system used by both Pitt and UPMC? Do they use the same system?*

Yes, both Pitt and UPMC can use the validated system for research purposes.

# Electronic Informed Consent (eIC)

*Can those compliance checks/build-ins for eIC be shared broadly for studies using eIC in the standard REDCap platform?*

eIC is available in both the standard and validated REDcap. Demo eIC projects can be made available for review upon request. It is important to note that only the REDCap validated system is Part 11 compliant.

# Access Levels

*Is HSIT handling development of DCFs only or entire project setup including events, form display logic, user roles, DAGs, notifications, queries, reports, API, etc., etc.? What kind of access level will research teams have vs. HSIT developers?*

In validated REDCap, HSIT handles building the DCFs, setting up events, form display logic, user roles, and DAGS. Queries are handled by compliance monitors from ECS-HSR. Research teams will have access to set up their alerts, notifications, and reports.

Additional Functionality

*Does the validated system have eTMF/ISF available? If not, is there a plan to include it?*

Electronic Trial Master File (eTMF) and Investigator Site Files (ISF) are not generated by REDCap and will still need to be maintained by research teams in Study Binders.

# Reports

*Does REDCap have a function to export the current data in SAS format for analysis?*

Yes, it does. You can export manually via reports or use an API within SAS to export directly.

# Presentation

*Could you please share this presentation with us?*

The complete presentation is available at <https://www.ecshsr.pitt.edu/ecs-hsr-video-presentations-library>.