27. RESEARCH ELECTRONIC DATA CAPTURE (REDCAP)

27.1 WHAT IS REDCAP?

REDCap is a secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data (including 21 CFR Part 11, FISMA, and HIPAA-compliant environments), it is specifically geared to support online or offline data capture for research studies and operations.

Licensed and installed at EVMS, REDCap is an institutional resource available to Faculty, Trainees, and Staff. EVMS requires that EVMS research data be maintained in REDCap. For the IRB, this includes human subject research studies and projects submitted to the IRB for determination of non-research, such as QA/QI when the data is collected locally. Large deidentified datasets from TriNetX, CDC, VHI, and other publicly available data sets do not need to transfer data into REDCap.

27.2 WHEN MUST REDCAP BE USED?

Any submission that collects Protected Health Information and requires an EVMS IRB determination or review is required to meet the criteria described herein, regardless of whether or not the project is human subjects research. Before final approval or determination will be released to the Principal Investigator, the Project ID and a live link to the site must be provided to the IRB office for confirmation.

All projects collecting PHI data must use REDCap. PHI may no longer be kept in Excel spreadsheets or other programs regardless of the security measures used. Data collected solely from partnering institutions such as CHKD and Sentara must meet that institutions requirements.

EVMS studies involving surveys or questionnaire, should use REDCap as best practice. However, it is understood that some tools are more easily designed and managed through Qualtrics. Qualtrics will allowed if approved by the IRB, and the study does not involve PHI. If the surveys or questionnaires are to be completed as a hard copy, then the data must be transferred to REDCap or Qualtrics and the original forms saved for auditing purposes. For ease, subjects should be given a link to complete the tools in REDCap or Qualtrics. If using REDCap, subject consent or agreement to participate can also be obtained within the program, reducing the paperwork that needs to be tracked.

Industry sponsored or collaborative projects where data is primarily housed at another institution, may use e-submission systems as identified in the written protocol. However, if data is initially housed at EVMS and then transferred to another location, the initial data saved at EVMS must be stored in REDCap or Qualtrics.

27.3 SPECIFIC REQUIREMENTS AND BEST PRACTICES WHEN USING REDCAP

The following ***best practices*** must be addressed in the IRB submission:

- All new projects must start with zero records. Any test data or pre-research data cannot be included in the actual Project ID (PID) for research data.
- All prospective data entered by subjects should have an ICF or Information Sheet at the entry point or in hard copy documenting the subjects were informed of the project and agreed to participate. The IRB determines if the project requires Informed Consent, an Information Sheet, or meets the requirement for a waiver of consent.
- If research team members are recording data directly into REDCap instead of the participant, the entry point should be a confirmation page that either consent was obtained or information was given to subjects and they agreed to the study. If the IRB issued a Waiver of Consent that should be noted instead.
- If data is collected via hard copies and then entered into REDCap or Qualtrics by research team members the hard copies must be dated, retained with the study records and provided for auditing upon request.
- Projects involving retrospective data and prospective data must have a method for identifying which records are retrospective and which are prospective.
- The IRB submission should clearly delineate what privileges each research team member will have in REDCap or Qualtrics.
    - Highest level privileges: Should be reserved for a responsible investigator (PI, Co-I or senior team member) and limited to a small number.
    - Privileges for all other research team members
    - Define Data Viewing Rights
    - Define Data Export rights
- For REDCap, each PID should include the regulatory approval number.
- If individuals from other institutions will have access to the data, their respective roles and access/privilege levels must be documented in the submission and a copy of their institution's IRB determination or approval is required to be submitted as part of the EVMS IRB submission. **Please note, in cases where an external collaborator was not involved in the collection efforts identifying information cannot be shared with collaborators outside of EVMS.**
- Each IRB submission must include a description noting how data will be maintained, access given or restricted, and all security measures in place.
- If there is a requirement to have a Subject ID Key to separate study data from identifying information, the Subject ID Key must be kept in a separate project.
- A project can only contain data for one IRB approved study. Any merging of data from multiple PID's must have an IRB approval that is obtained prior to any merge.

27.4 AUDITING / COMPLIANCE

Projects and any associated data and records may be audited or reviewed by EVMS auditors or regulatory staff as needed and without prior notification.

27.5 REDCAP REQUIRED CITATIONS

Investigators must cite the information and publications below in study manuscripts using REDCap for data collection and management. REDCap recommends the following boilerplate language:

> Study data were collected and managed using REDCap electronic data capture tools hosted at [YOUR INSTITUTION].[1,2] REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.
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> [1]PA Harris, R Taylor, R Thielke, J Payne, N Gonzalez, JG. 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.*
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> [2]PA Harris, R Taylor, BL Minor, V Elliott, M Fernandez, L O'Neal, L McLeod, G Delacqua, F Delacqua, J Kirby, SN Duda, REDCap Consortium, **The REDCap consortium: Building an international community of software partners**, *J Biomed Inform. 2019 May 9 [doi: 10.1016/j.jbi.2019.103208]*

27.6 PARTNER INSTITUTIONS USING THE EVMS IRB

Children's Hospital of the King's Daughters (CHKD) has a separate REDCap account that should be used for research located solely at CHKD.

Sentara has a separate REDCap account that should be used for research located solely at Sentara.

In these cases, not all of the above requirements need to be met. Contact the appropriate institution for specific requirements.

Collaborative projects between EVMS and another institution should follow the process determined by the PI's primary affiliation or as required by the IRB.

In summary, all projects involving data from a medical record must use REDCap for data storage and incorporate the above requirements and best practices. Projects not involving PHI or medical record data may use Qualtrics if approved by the IRB.