A Solution to Creating and Managing your Regulatory Binder Electronically

The majority of clinical trials require the maintenance of essential documents in what is referred to as a Regulatory Binder. With the trend towards electronic recordkeeping, there is increasing interest among sites to create and manage essential documents electronically. Although most sites would prefer to have a complete electronic process, QI program on-site experience indicates that a hybrid of print and electronic files is common. When documents are stored across locations, as in the hybrid model, additional attention is required to prevent potential problems with staff access, document completeness and accuracy.

Problem

The results conducted by the Hybrid Model indicate that a hybrid of print and electronic files is common. When documents are stored across locations, as in the hybrid model, additional attention is required to prevent potential problems with staff access, document completeness and accuracy.

Partnership

The QI Program and ERIS collaborated in 2014 to develop a comprehensive electronic template for creating and managing essential documents that prevents potential problems of the hybrid model. The template merges the QI and ERIS commitments to provide:

- support and education to ensure the optimal conduct of human subject research within the framework of federal regulations, institutional policies and good clinical practice guidelines (QI)
- applications, processes and resources that support the basic, biomedical and clinical research missions (ERIS)

Solution

The Electronic Regulatory Binder (eReg Binder) template assists sites with the electronic creation, storage and maintenance of essential documents for IRB approved protocols. The eReg Binder template uses features inherent to Vanderbilt University’s REDCap application and plug-ins developed by the ERIS team. With the REDCap User Rights interface, principal investigator or designated staff can grant varying levels of access to essential documents based on an individual’s role or task.

The template is unique in that it contains:

- Data collection forms that capture essential documents similar to what is generally captured in the print Regulatory Binder. Each form contains logic that identifies and collects applicable regulatory information.
- Custom programmed project reports (e.g. delegation of responsibility, protocol amendment tracking and consent version tracking logs)
- Custom programmed calendar alert system that automatically transfers dates to the REDCap calendar for keeping track of regulatory document due-dates

Results

The eReg Binder template was piloted in November 2014 to a sub-set of users from a variety of departments before its release to the wider Partners research community in January 2015. Overall, the template has received positive feedback from sites who found it easy-to-use and are interested in using it as the "official regulatory binder" for their study. From January to September 2015, 138 sites requested the template for a range of studies. Given the feature to access/review documents remotely, the project has also garnered the attention of coordinating centers responsible for large multi-site studies and from researchers at other institutions.

Scalability

The eReg Binder project template will be made available to the REDCap consortium in 2015 which has over 1500 active institutional partners. The project includes plug-ins which allow developers to hook into REDCap’s framework when building custom code without having to actually modify the base code. This will allow any participating consortium member to implement the eReg Binder template at their institution. The next version of the eReg Binder will contain additional enhancements that allow sites to enter unlimited study management related information (e.g. study staff information, protocol and consent form version information) into the REDCap project, prompting automatic updates to the project build and plug-in reports.

Access

To access the REDCap software and view participating institutions and administrators: http://project-redcap.org/. The eReg Binder project template and custom plug-ins are compatible with REDCap v5.9 and higher. A REDCap Administrator can create an eReg Binder project template via instructions on Github: https://github.com/phseris

Acknowledgements: The eReg Binder project template was developed using REDCap electronic data capture tools hosted by Partners ERIS group. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies. 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.