Ascension Wisconsin

Research Integrity and Protection Newsletter

July 2017

Prefer Electronic Documents? Don't forget your audit trail!

Electronic documents must show an audit trail, much like that of paper documents that are maintained in the research setting. So, if you are maintaining source documents electronically- like the screening and/or enrollment log or drug accountability log- you must have an audit trail of each change. One way to do this would be to save a new version each time there is an addition, deletion or revision made to the log (all versions must be available to a reviewer).

A few related references include:

- FDA guidance on electronic source documents- references CRFs specifically, but can be applied to all source documents.
- NCI PMB drug accountability training videos and handouts- specifically state if you are using electronic logs, the must be auditable.
- ICH GCP 4.9.4 The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirement(s). The investigator/institution should take measures to prevent accidental or premature destruction of these documents.
    - 8.3.13 SOURCE DOCUMENTS To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject.

Forwarding your Screening Logs to the Sponsor? The IRB needs to know!

Sponsors sometimes request that sites send in screening logs as a way to assess recruitment activity. But did you know that you may be providing the Sponsor with private health information (PHI)?

If your log includes an identifier (like initials or service dates) *and* health information (like a test result to describe why they are not eligible) - then the form includes PHI and cannot be sent to the Sponsor (or outside the institution) under the preparatory to research clause of HIPAA.

If PHI needs to be accessed or collected prior to getting consent/HIPAA authorization *and* sent to the Sponsor, Ascension IRB would need to grant an ICF and HIPAA Waiver for the recruitment portion, as required by the Federal regulations for human research protection and the HIPAA Privacy Rule.

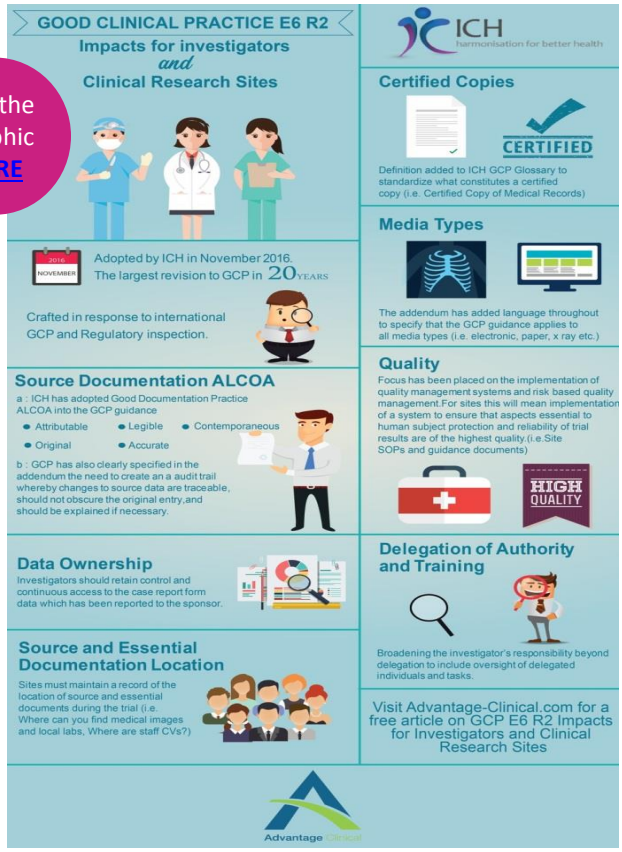
This activity needs to be described, and waivers requested, in the IRB application.

If the study is already approved and logs including PHI are forwarded to the Sponsor- and the study is still open to enrollment- file an amendment with Ascension IRB to update the description of the recruitment process and request the needed waivers.

Good Clinical Practice E6 Revision 2

Revisions have been made to GCP for the first time in 20 years! Check out the infographic below to see the impact on your work.

Get the graphic HERE



Questions? Comments? Contact Research Integrity and Protection at RIPO@Ascension.org