



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.

GOOD CLINICAL PRACTICE E6 R2
Impacts for investigators and Clinical Research Sites

Get the graphic [HERE](#)

Certified Copies
Definition added to ICH GCP Glossary to standardize what constitutes a certified copy (i.e. Certified Copy of Medical Records)

Media Types
The addendum has added language throughout to specify that the GCP guidance applies to all media types (i.e. electronic, paper, x ray etc.)

Quality
Focus has been placed on the implementation of quality management systems and risk based quality management. For sites this will mean implementation of a system to ensure that aspects essential to human subject protection and reliability of trial results are of the highest quality (i.e. Site SOPs and guidance documents)

Delegation of Authority and Training
Broadening the investigator's responsibility beyond delegation to include oversight of delegated individuals and tasks.

Source Documentation ALCOA
a. ICH has adopted Good Documentation Practice ALCOA into the GCP guidance
• Attributable • Legible • Contemporaneous
• Original • Accurate
b. GCP has also clearly specified in the addendum the need to create an audit trail whereby changes to source data are traceable, should not obscure the original entry, and should be explained if necessary.

Data Ownership
Investigators should retain control and continuous access to the case report form data which has been reported to the sponsor.

Source and Essential Documentation Location
Sites must maintain a record of the location of source and essential documents during the trial (i.e. Where can you find medical images and local labs, Where are staff CVs?)

Adopted by ICH in November 2016. The largest revision to GCP in 20 YEARS.

Crafted in response to international GCP and Regulatory inspection.

Visit [Advantage-Clinical.com](#) for a free article on GCP E6 R2 Impacts for Investigators and Clinical Research Sites