

E-mail GLP Compliance



Renée Daniel
Perspective Consulting
NAICC 2008

Is Email Raw Data ?



Definition of Raw Data

- Any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are result of *original observations* and activities of a study and are *necessary for reconstruction* and evaluation of report of that study

40 CFR part 160.130

Definition of Raw Data

- " Raw data" may include photographs, microfilm or microfiche copies, computer printouts, any original data captured electronically or by some other medium, dictated observations, and recorded data from automated instruments

40 CFR part 160.130

Key Determining Factors

- Does the email information contain original observations? For example,
 - Explanation of something that occurred in the study that either goes beyond what is explained in the study data or that is written prior to recording the information in the study data
 - Plot observations or crop status update to study director that is not recorded in study data or recorded in email first.

Key Determining Factors

- Could information in the email be necessary in reconstructing the study or evaluating the report of the study? For example,
 - If EPA auditor asked PI a question about something that occurred in a study, would the email information be needed to help explain the situation above and beyond what is written in the study data (very common with electronic field notebooks)?
 - Study Director sends email changing study but no amendment received yet

Key Determining Factors

- Does email provide proof not provided by study data indicating that protocol or SOPs were followed? For example,
 - Protocol requires sending electronic notebook to sponsor within 1 week of critical event. Process of preparing to send is recorded in e-notebook but there is no record that data was actually emailed.
 - Protocol requires PI to inform sponsor when samples are shipped. Email may be only record that sponsor was informed.

Who Should Be The Judge?

- STUDY DIRECTOR
- STUDY DIRECTOR
- STUDY DIRECTOR
- Most of the time!

How Should Email Be Handled?

- Read and respond immediately
- Print out
- Initial and date (optional, unless email is raw data being printed out by the generator)
- File with study data
- Do not depend on Study Directors to put emails in the study file
- Assure that QA has access during inspections/data audits

Other Critical Issues

- If email information changes protocol assure that deviation/amendment is written
- Review all emails prior to sending notebook to assure that copies of all critical emails are with the paper data (especially for studies conducted with e-notebooks)
- Keep study director in the loop
- If in doubt, print, initial, date, file with data