

An aerial photograph of a vast agricultural field, likely a seed production field, showing distinct rows of green and reddish-brown plants. A red tractor is visible in the upper center, moving through the field. The image is overlaid with a large, white, rounded rectangular shape that contains the main text.

Originals vs True Copies: Should CRO's keep or toss originals?

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Agenda

History of the Original and True Copy

How would you handle these situations?

Final tips & takeaways

History of the original and true copy

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Why and When did this come about?

EPA advisory #83

Response to a letter dated August 24, 2011, about the EPA's opinion regarding the retention of copies of raw data rather than original copies.

[Where to find: Interpretation of the Good Laboratory Practice \(GLP\) Regulation: GLP Regulations Advisory No. 83](#)

So what did it say?

- “The format, method and process used to copy and retain those copies will be key in determining whether or not [said company] has met its obligations to ensure that the copies are “true” and that they will be available in the future for inspections.” from URL address above.
- Specific 40 CFR Part 160 areas mention: 40 CFR 160.195(i), 40 CFR 160.3 defines “raw data”, and 40 CFR 169.3(a).
- Also mentions example about forensic information could be lost

How did the EPA feel about it?

It is consistent with the requirements of 40 CFR Parts 160 and 169 regarding the retention of true copies of raw data paper records instead of the original paper records.

So what does this mean?

- Are all true copies the same? Why?
- Can CRO's throw away the originals?
- What about electronic raw data?
- What do we think some good practices would be for creating true copies?

Final Takeaways and Tips

- Check with Sponsor to throw away originals
- Be mindful when creating and preserving your true copy



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