Clinical Research Documentation

ALCOA PLUS Checklist

"If it wasn't documented, it wasn't done."

A	L	C	O	A
Attributable It should be obvious who created a record & when. It should be obvious who made changes, when & why.	**Legible** The research data should be easy to read.	**Contemporaneous** Data should be recorded as it is observed. All signatures/ initials should be dated.	**Original** Study records should be originals, not photocopies.	**Accurate** For data to be viable it should be error free. Data quality must be maintained.

P	L	U	S
Complete Data should feature a trackable audit trail to prove nothing has been deleted or lost.	**Consistent** Data should be chronologically arranged, with time stamps included for any addition to the original data.	**Enduring** The material used to record data should last a long duration without losing readability.	**Available** Data should be accessible in a readable format whenever needed, over the life of the data.