

CRA Audit Notes

A Comprehensive List of Pre-Printed Phrases



All include a 'Done' checkbox for the Study Coordinator to check once the action is completed.



Please Complete...

Check boxes include: Date (As Late Entry); Header; Initials; Page Number; Patient Number; Signature (As Late Entry); (Blank) Section for Completion



Blank

Check boxes include: Done; Late Entry



Protocol Deviation...



Serious Adverse Event...



Per the Source...



Adverse Event of Special Interest...



Please Reconcile...



Adverse Event...



Prior to the Next Visit...



Please Add to Drug Accountability Log...



Per the eCRF...



Concomitant Medication...



Please Clarify...



Temperature Excursion...



Please File...



Please Report to IRB/EC...



