ISCT Example: Source Document Review Requirements

General comments:

1.      Adding it to personnel log or role delegation log as a QI or SI responsibility can’t hurt

2.      This is sample of how a protocol would read

3.      Also a sample of how labs should be reviewed for e and paper version

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| --- | --- | --- | --- | --- |
|   | Measure | Record on CRF/eCRF | Annotate as CS or NCS on CRF | Annotate as CS or NCS in source documents |
| Hb | ✓ | ✓ | 3 | 3 |
| ANC | ✓ | ✓ | 3 | 3 |
| Platelets | ✓ | ✓ | 3 | 3 |
| Other heme values | 1 | 2 | 3 | ✓ |
| AST | ✓ | ✓ | 3 | 3 |
| Other LFTs | 1 | 2 | 3 | ✓ |
| 1.      Only if clinically indicated or centre practice2.      Only if considered clinically significant (i.e. requiring dose modification or resulting in symptoms) and related to protocol therapy; [depending on trial management may add as a lab value or as an adverse event]3.      Not required for this protocol.  For labs required by the protocol causality will not be reported but incidence by arm reported |

 CS = clinically signficicant: NCS = Not clinically signficiant