Mandatory fields and Forms

When creating the CRF for a BH and QMUL Sponsored CTIMPS, certain forms are considered Mandatory, and should be included in all CRFS.

These can only be omitted with written permission from the Governance Operations Manager.

These include:

- Inclusion and exclusion criteria(confirmation the participant is eligible)
- Consent details (date, version etc.)
- AE Reporting form
- Concomitant medication
- Treatment Form/Dosing and Compliance data [^dose]
- Withdrawal/Completed study form
- Death
- Per visit and follow-ups form (detailing dates of each visit or procedure)
- Principal Investigator sign off statement

Additional recommended forms

- Relevant Medical History
- Patient Demographics
- Physical Examination and results
- Baseline data as stipulated by the protocol
- Randomisation/registration
- Relapse/recurrence
- End of Treatment form (end result of study)
- Lab data, ECGs, etc.

SOP 38b Associated Document 1 - CRF Design Guidance

The following has been taken from SOP 38b AD 1, for more information please click here