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Research Development & Support

16th August 2019

CRF training/guidelines

- **Identify** the mode of CRF completion – paper, electronic or both.

If electronic:

- Is the system secure, password protected, backed up, auditable, and does it have the ability to create and assign user accounts (so that only those delegated may access and use the system)?
- Does the electronic system store metadata, as required by Good Clinical Practice (GCP)?
- Does the system have the ability to perform data validation checks, range checks and consistency checks?
- Does the system have the function to automatically raise data queries should any data be missing or be incorrectly entered/unsuitable for the field?

CRFs should only be completed by those staff delegated this duty.

- In **designing** CRFs, the following sections/pages are advised*:

1. Screening visit;

2. Eligibility *(including a space for PI or Co-Investigator sign-off)*;

3. Confirmation of consent, medical history etc. *(including a space for PI or Co-Investigator sign-off)*;

4. Randomisation;

5. Treatment visit(s);

6. Drug accountability/treatment (*there should be space for recording dose administration, kit numbers, IMP compliance and amount of returned IMP*) ;

7. Follow-up visit(s);

8. Unscheduled visit(s);

9. Laboratory results *(including a space for PI or Co-Investigator sign-off)*;

10. Final study visit/study completion;

11. CRF sign-off page.

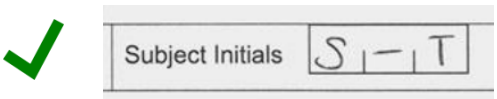
*Within the CRF pack, there should also be a CRF page for protocol deviations/violations, in addition to (if applicable) safety reporting, and death.

- Ensure that CRFs include as little personally identifiable information as possible, as these documents are subject to monitoring by the Sponsor, and as such identifiable information should be kept to a minimum.

Top tips/items to remember

- CRF documents should be version controlled, dated and paginated.

- Dates should be collected as dd-mmm-yyyy, e.g. 01-OCT-2017.
- Time should be collected in 24 hour clock.
- Do not leave any blank spaces on the CRF when completing, otherwise this will result in a data query until this space is filled in. If the data is not available, applicable, or the procedure was not carried out, then the box may be filled with NA, NK or ND (not applicable, not known, and not done).



Images taken from NIHR
Good Clinical Practice training content

- Errors should not be scribbled out, rather crossed out with a single line, initialled and dated.
- Do not use tippex, and do not use post-it notes.
- Do not make up data! The source data should be used when completing CRFs.

- If site staff are completing CRFs, then they should be provided with CRF completion guidelines, including:

  - When to complete the CRF;
  - How to complete the CRF;
  - The correct units for any data that is required;
  - List accepted abbreviations;
  - How to correct data in the CRF;
  - What to enter when no data is available;
  - How/when the CRF should be sent to the sponsor, or researcher;
  - Key reference ranges;
  - Contacts for support in CRF completion.

- Amendments to CRFs are not subject to approval by the HRA, NHS REC, or MHRA – as they usually accompany a change in the protocol (change to research design, scientific value etc.) which already constitutes an amendment.

- New CRF documents should be filed in the TMF, alongside clearly marked superseded versions.