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Tips for becoming 'audit-ready'

Study Documentation/Record Keeping

- The Principal Investigator (PI) should date and sign study protocols filed in the Investigator Site File (ISF) in a timely way to show agreement to conduct the study in line with the protocol. Ensure all Manuals and Investigator Brochures stored in the ISF are also signed by the PI.

- Ensure all superseded documents are clearly marked as such and signed and dated in a timely way to confirm the changes that took effect at the site.

- Use an Amendment Log and Version Control Log to keep track of Amendments and document version numbers/dates. See example Amendment Log and Version Control Log.

- Medical records/patient notes should contain full details of study involvement including the results of investigations conducted (which should be signed off appropriately). Ensure all staff in the team are aware of the need for good record keeping including signing and dating all annotations in medical records, ensuring legibility of annotations and using single line through corrections with initials and dates (in compliance with GCP).

- When new Patient Information Sheets (PIS)/Informed Consent Forms (ICFs) are implemented following an Amendment, ensure that patients are re-consented at the next available opportunity (next study visit, unless it is necessary to implement this sooner). Ensure that all Amendments are implemented in a timely way and all members of the study team are made aware of what the Amendment involves and the actions that are required.

- Ensure that all staff members are aware of Amendments and sign the relevant training log to document training completion.

- Good Document Practice and GCP require that where boxes are provided on Case Report Forms (CRFs) and ICFs these should always be completed. If not applicable, this must be written in the appropriate space (and justification included, if necessary). All entries on CRFs should be signed and dated appropriately.

- All annotations in medical records must be signed, dated and attributable to the person completing the activity. Each NHS Trust will have a policy addressing good record keeping – ensure that all staff are aware of and comply with this.

- Ensure alert forms/stickers are used consistently throughout patient medical notes to highlight the fact that the patient is participating in a clinical trial.

- There should be evidence of PI oversight within the source documentation and ISF.

Delegation

- Staff members must be added to the delegation log and their entry signed off by the PI in a timely way. Staff members should not perform any study-related duty before being added to the delegation log and their entry signed off by the PI.

- Staff members should only be assigned duties that they are appropriately trained to perform. The PI must sign off all entries to indicate that duties have been delegated appropriately. Relevant training certification should be filed in the ISF.

- Staff members must be removed from delegation logs (an end date entered and signed off by the PI) in a timely way, to ensure that this document is kept up to date.

- Produce a File Note for any staff name changes e.g. due to marriage, including the date of the name change to ensure consistency of records.

- Ensure that all tasks for each study are covered by the delegation log – add these to the log if necessary. The Newcastle team is currently developing a list of key tasks that should be covered on every delegation log. This will be shared when it is available.

- Ensure all current staff on the delegation log have GCP training (valid within 3 years, or less depending on local Trust guidelines) and that there is evidence of GCP training for all staff to cover the full period of their involvement in the study.

- Ensure all current staff have a signed and dated CV (valid within 2 years, or less if local guidelines dictate) and all staff have CVs to cover the full period of their involvement in the study.

- Ensure superseded training documentation is clearly identified and segregated from current documents.

- Ensure that informed consent is received only by staff in those groups detailed in the IRAS/HRA application. When filling in the IRAS form, ensure that the appropriate staff roles are included for each study activity (avoid specifying individual staff names unless certain they will be working on the study – it is better to include roles such as appropriately qualified Study Doctor, Research Nurse, Physiotherapist etc.)

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Eligibility and Enrolment

- To ensure that it is clearly documented that each patient recruited meets the eligibility criteria, ensure that an up to date eligibility checklist is in use and is appropriately filled in, signed/dated and filed in the medical notes. This should state that the patient meets all of the inclusion, and none of the exclusion criteria, and is eligible to participate in the study.

- Ensure that the screening and enrolment logs for each study contain a space to record the details of the person who screened/enrolled the patient.

Consent

- Ensure that each member of staff that will be receiving consent is appropriately trained to do so and has this activity appropriately delegated on the delegation log.

- If a patient is capable of writing they should complete their own personal details on the ICF. If the patient is not capable of writing and their consent is being documented by a witness/representative, this should be clearly documented and justified.

- Ensure that all details are completed fully on the ICF. The ICF must be signed and dated by both the participant/representative and the person obtaining the consent. The date entered by the person giving and the person receiving consent should match, or if they do not, the reason why should be fully documented. Consider asking another appropriately qualified member of the study team (e.g. Doctor, Research Nurse, Physiotherapist) to perform a check of the completed consent form to confirm that it has been filled in fully and correctly.

- A copy of the ICF should be given to the patient, a copy put in the medical notes and the original stored in the ISF.

- Full details of the consent process should be documented in the patient's medical notes, along with a copy of the PIS and ICF. The following details should be documented:
    - The method of consent e.g. written, by telephone (must be approved by REC)
    - The version number and date of the PIS and ICF that have been reviewed and signed by the patient
    - That a copy of the PIS/ICF was given to the patient
    - That time was given for questions and the patient had sufficient time to review the information and decide whether or not to participate (document how long)
    - That the right to withdraw was discussed
    - The date and time when the ICF was signed and confirmation that the patient agreed to participate.

  - That any legislative documents e.g. information about GDPR were given to patients and time was allowed for questions

These details should be documented with appropriate signature, time and date entered by the person receiving consent. Any study-related procedures should be carried out/documented only after consent has been received.

- Re-consent to amendments should also be documented fully (as above).

- The participant must confirm that they are willing to take part in the study (this must be included in the design of the consent form).

- It is also good practice to document in the medical notes at each study visit that the patient has agreed to continue participation in the study.

- Where the version number of the PIS is referenced on the ICF, ensure that the correct version is documented. The ICF and PIS must be the current version in use with appropriate approvals in place.

- Ensure that patients initial rather than tick the boxes on the ICF to indicate consent. All of the consent statements must be initialled by the participant or their representative.

Safety Reporting

- Use an appropriate Adverse Event (AE)/Serious Adverse Event (SAE) tracking log to record all AE/SAEs for each study. Include spaces to record the name of the member of staff recording/addressing each AE/SAE, their signature and date for each item on the log. The log should enable tracking of reporting, follow-up and completions, ensuring tasks are attributable.

- All SAEs must be reviewed by the PI and annotated with initials and date to confirm that actions have been completed.

General

- It is a good idea to conduct regular audits on the ISFs that you maintain to ensure that they are kept up to date. Contact your local R&D Office to ask for an audit template that could be used as a guide when reviewing your files.
- When a study is regularly monitored by/on behalf of the Sponsor (e.g. by a Contract Research Organisation), ensure that time is scheduled during each monitoring visit for the monitor to speak to key members of the study team e.g. Principal Investigator, Study Doctor and Nurse, Physiotherapist, Trial Coordinator, Data Manager etc. This should ensure that any issues are dealt with promptly and that the ISF is kept up to date.