Guidelines for Minimum Casenote Documentation Requirements

It is important that all aspects of clinical care continue to be documented and that clinical trial data which is relevant to the ongoing care of the patient is documented in the patient's medical records. It is also important that it is obvious from the casenotes that the patient is in a clinical trial and how the PI can be contacted for any clinical queries.

Trial recruitment and entry

As a minimum, the following needs to be noted in the patient's medical record when a patient is approached about the study or recruited:

- Name of trial
- Date approached about study or PIS given
- Copy of PIS
- Date of consent + record of discussion to show patient is 'informed'
- Copy of signed consent form
- Trial ID number
- Arm they've been randomised to
- Name of PI to contact about the study if there are any issues

Trial clinic visits

As a minimum, the following needs to be noted in the patient's medical record when a patient has a trial-related visit:

- Date and study visit number e.g. STOP-ACEi baseline visit
- Any clinically relevant information e.g. medical history, changes to treatment/prescriptions, results of any medically relevant trial assessments
- For AEs, a brief description of the event inc. start/stop dates and results of any clinically pertinent assessments made relating to the AE.

Identifying trial participants

It is also necessary for there to be a system in place that will alert any other clinical staff of the patient's participation in a clinical trial e.g. a sticker in their physical casenotes or an electronic alert in their electronic records.

STOP-ACEi Trial Office:

If there are any issues in meeting these requirements, please contact the STOP-ACEi trials office:

Birmingham Clinical Trials Unit (BCTU), University of Birmingham, Edgbaston, Birmingham, B15 2TT.
Tel: 0121 415 9130 | Fax: 0121 415 9135 | Email: STOPACEi@trials.bham.ac.uk.