Appendix 6

Data collection, management and confidentiality

Data collection

Paper Case Report Forms (CRF) and study questionnaires are the primary data collection instruments and treated as source data. All data requested in the CRF will be recorded. All missing data will be explained. Data captured in the paper CRFs will then be entered into a validated web based database under the management of LCTU. On-entry validation checks will be applied where required and data entered will be checked for completeness, accuracy and timeliness by the study team/trial manager/data manager. All study visits and AEs will be recorded in the hospital notes.

Data management

All study documentation containing identifiable patient data will be managed in accordance with ICH-GCP, the UK Policy Framework for Health and Social Care Research and the Data Protection Act (or its subsequent legislation) and made available for inspection, monitoring or audit purposes by the Sponsor, host, regulatory authorities or the funder. All electronic data will be stored in secure network drives, to which only the relevant study staff have access. All study documents and data will be kept for 15 years or the minimum determined by the regulatory authorities, whichever is the longer.

Data confidentiality

Each participant will be assigned a unique identification number upon recruitment. Participant's contact details will be held on database separate to the study visit data and used to arrange data collection visits. The database will be password protected and only researchers collecting data will have access. All data collected during the study will be stored anonymously on a separate database. Again access will be password protected and restricted to relevant members of the research team. Paper copies of the CRFs and questionnaires will be stored in a locked filing cabinet in the relevant research office. The study research team will comply with the Data Protection Policy of the University of Leicester and local NHS Trusts.