TARDIS – Working Practice Document No: 031

Version control of Trial Documents

Trial specific documents are prepared by the Coordinating Centre (CC) and are version controlled and dated.

Some trial documents (PIS, RIS, Independent Physician Information, Consent forms, GP letter) require ethical approval. In the UK this involves MREC approval.

Information Sheets and Consent Forms
Approved versions must be always be used and should be printed on the headed notepaper of the recruiting hospital.

In the UK, the CC will obtain MREC approval for new and updated documents and will then distribute the documents to UK sites by either email and/or make available on the TARDIS website (http://www.tardistrial.org). Copies of the MREC approval letter and approval of any subsequent changes will be available on the website. Each hospital site must inform their local Research & Development Department of the changes prior to implementation.

Following this, the new version should be used with all patients and one copy of the old version should be archived in the site trial file. Extra copies of the 'old' versions should be destroyed to prevent inadvertent use.

Documents for use with Patients
It is not permitted for any UK site to use documentation for patient's use that has not been prepared by the CC and had ethical approval.

Forms
SOPs are created by the Sponsor, University of Nottingham. Trial Working Practice Documents(WPDs), and other Forms are prepared by the CC, version controlled, dated and posted on the TARDIS website as they become available.