

## **King's Health Partners Clinical Trials Office**

### **Version Control Guideline**

#### **INTRODUCTION**

This document is intended to provide guidance to members of the KHP-CTO and partner institutions on the version numbering and amendment of documents used in the administration of Clinical Trials. Version control ensures that amendments to documents are tracked and verifiable and that the correct version of a document is in use according to the relevant ethical, regulatory or local approval.

#### **APPLICABLE TO**

This guidance document is applicable to all documents produced by the KHP-CTO, including but not limited to SOPs, Template documents and Training Presentations. It may also apply to documents produced by Investigator sites, including but not limited to Clinical Trial Protocols, Patient Information Sheets (PIS) and Consent forms, Investigator Brochures and Case Record Forms.

#### **CONVENTION**

All documents will be given a version number X.X; e.g. Version 1.0

Each amendment to a document will require the version number to be updated.

If this is **significant change** e.g. change in the content of the document, then the version number should be increased by 1.0.

i.e. **Version 1.0** would change to **Version 2.0**

If it is **minor change** e.g. contact details, the number after the decimal point should be increased by 0.1.

i.e. **Version 1.0** would change to **Version 1.1**

Amended documents should only be used following the applicable regulatory or ethical review.

Each version should be dated on the day on which it is created; to prevent ambiguity the date format DD-MMM-YY should be used e.g. 10-Jan-08

#### **SPECIFIC GUIDANCE FOR USE IN MULTICENTRE TRIALS**

Where a document, such as a Patient Information Sheet (PIS), is to be used across several sites then a central version number (and date) should be used, if necessary a local version number and date may be required where the local version number reflects the individual site details (normally contact information).

e.g. PIS version 1.0, 10-Jan-08 (local version 1.0, 10-Feb-08)

In the event that the individual site contact details change, the central version number remains the same and the local version number will be increased by 0.1

i.e. The above example becomes: PIS version 1.0, 10-Jan-08 (local version 1.1, 10-Mar-08)

In the event that the central version changes, on addition of the individual site contact details the local version number is updated to reflect the change in central version number.

i.e. The above example becomes: PIS version 2.0, 20-Jul-08 (local version 2.0, 30-Aug-08)