

Standard Operating Procedure

<b>Title: REVIEW OF PROTOCOL AMENDMENTS</b>		
<b>REF: SOP 011</b>	<b>Version: 04</b>	<b>Issue No: 1</b>
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Approved by: Dr M J Maxwell		Date: 21/05/07
Due for Revision		Date: 05/11/2012
This SOP is effective from:		Replaces: Version 03 (21/05/07)

## 1. BACKGROUND

It may be necessary during the course of the study to make amendments to the protocol. For example, adverse events may occur which make an adjustment to the dose of the study medication necessary; or extra patient assessments may be included.

## 2. PURPOSE

To describe the procedure for reviewing any proposed changes to the protocol that may be introduced during the study.

## 3. OTHER RELATED PROCEDURES

SOP 004      Submission to Research Ethics Committee  
 SOP 006      Study Files and Filing

## 4. WHEN

Staff should be made aware of the proposed amendment as soon as it is available; however, whatever changes the amendment may contain must not be implemented until written approval of the amendment is received from the appropriate Research Ethics Committee.

Note: in the event that an immediate amendment of medication or dosing is essential for patient safety, the Investigator may initiate the change without waiting for approval from the REC, but must notify the REC within 3 days of so doing.

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## **5. WHO**

The Principal Investigator at each site must check all amendments, and must ensure that staff are informed of the amendment and are fully aware of its content.

## **6. HOW**

Where there is need for the introduction of an amendment to the protocol, this should be in consultation with all relevant parties and the Sponsor.

Amendments may be presented in different formats: as an additional supplement page or the whole protocol may be rewritten as an amended version. If the amendment is presented as a loose page or pages, it is recommended that this is clearly annotated in the appropriate part of the original protocol and that these are kept together.

If the protocol is rewritten as a new version, the old version should be filed safely in the Study File and clearly marked as superseded and on what date.

The Research Ethics Committee approved version of the Patient Information Sheet and Informed Consent Form should be checked against the protocol amendment and these documents amended as necessary.

The appropriate Research Ethics Committee must be informed of the amendment and this should not be implemented without documented approval from the committee. This also applies to the Patient Information Sheet and Informed Consent Form if they have been amended.

In the case of multi-centre studies, the letter from the appropriate Research Ethics Committee detailing their approval of any amended documents will indicate if submission to the local Research Ethics Committee that conducted the Site Specific Assessment is required.

All amendments should be sent to the R&D Department of each Study site to assess the impact of the amendment on the conditions of NHS approval.