

Pharmaceutical
Research Centre

STANDARD OPERATING PROCEDURE

7 ALLOCATION OF STUDY IDENTIFICATION

VERSION 2

REASON FOR REVISION: CHANGE IN PROCEDURE

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DATE: 02/06/2006

1 INTRODUCTION

- 1.1 The purpose of this standard operating procedure is to describe the approved procedure for the allocation and use of unique study identification for all studies performed at Pharmaceutical Research Centre.
- 1.2 This procedure has been designed for the management of studies and allows study number generation with the minimal data entry, the viewing and editing of studies entered, with the ability to sort any data. The system will provide number generation by any authorised user and its correct use will prevent study number duplication.

2 RESPONSIBILITIES

The Management Group are responsible for the implementation of this procedure.

3 ALLOCATION OF STUDY IDENTIFICATION

- 3.1 Study identifiers are allocated by an electronic auto-generating system, this provides the means for the input of basic information to create new studies, and the means to edit and view entered studies. The number is allocated in ascending numerical order indicating individual studies. The study identifier is the fundamental identification required for the work whilst in progress, on reports and in archives. Care should, therefore, be taken in the correct allocation of study identifiers and in their subsequent display on study documents.
- 3.2 Information recorded for each study is as follows:
 - Study Identifier
 - Study Type
 - Test Material Name
 - Study Director

➤ Sponsor Identification

4 USE OF STUDY IDENTIFIERS

- 4.1 A study identifier must be allocated by this system prior to its use in any correspondence or documents.
- 4.2 The allocated study identifier will be used to identify individual studies and will be referenced on the appropriate protocol or study plan. Before signing the protocol or study plan the Study Director should check that the study identifier is correct.
- 4.3 The study identifier will be used on the work-flow schedule, all data sheets, study records, cage labels, test vessels and any appropriate glassware. A number of leading zeros may be appropriate on both elements of the study identifier for some computerised records; these may be omitted in other situations.
- 4.4 If a study identifier has been allocated and the subsequent investigation are cancelled these study identifier will not be re-allocated.

5 APPROVAL TO COMMENCE WORK

The Study Director must approve the study plan, by dated signature, before any study specific work may be performed or data gathered.