Dorset HealthCare University NHS Foundation Trust

Standard Operating Procedure for Use of Investigators' Brochures

Objectives	The objective of this SOP is to outline the use of Investigator Brochures.
Scope	Applicable to all research staff involved in a Clinical Trial of Investigational Medicinal Product (CTIMP).
Responsibility	It is the responsibility of the Principal Investigator to ensure adherence to this SOP.
Related Document	SOP RES/015 – Pre-Study Monitoring Visits SOP RES/004 – Study Files and Filing

1 Purpose

This Standard Operating Procedure (SOP) explains what an Investigator Brochure is, why we have one, what it is used for and how we use them in clinical trials at Dorset HealthCare University NHS Foundation Trust.

2 Introduction

The Investigator's Brochure (IB) or the equivalent information must be supplied by the Sponsor to each study centre taking part in a clinical trial. It contains all the relevant information known prior to the onset of a clinical trial including chemical and pharmaceutical data, toxicological, pharmacokinetics and pharmaco-dynamic data in animals and the results of earlier clinical trials. There must be adequate data to justify the nature, scale and duration of the proposed trial.

The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial.

The GCP Directive requires that the brochure is validated and updated at least annually by the Sponsor.

It may be the case that for Phase IV studies no Investigator's Brochure is supplied because the drug is already registered with the authorities (i.e. has a Marketing Authorisation) and the Summary of Product Characteristics will be used instead.

3 Training

New users must read and understand this SOP before carrying out this procedure. Existing users must read and understand the Revisions Section

4 Revisions

This is the first version of this SOP. No revisions have been made.

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5 Procedure

5.1 For all studies with investigational products, i.e. not registered, an Investigator's Brochure must be provided.

5.2 All Investigators must know where the Investigator's Brochure is kept.

5.3 An up to date copy should remain with the Investigator's Research Department and, ideally, with the Pharmacy Department. Additionally, a copy may be submitted to the Trust R&D Department. It is the Sponsors responsibility to ensure that the Ethics Committee, Regulatory Authorities and each participating site receive updated copies of the Investigator Brochure.

5.4 If any new information arises during the trial, the Monitor must supply the department with an update or a revised version of the Investigator's Brochure. The Principal Investigator must ensure that all Investigators are familiar with the updated Investigator's Brochure.

5.5 When trials send out updated IB's they will normally require a receipt to be signed and sent back to the trials office. This should be carried out promptly and copies retained in the Investigator Site File.

N.B. The Investigator's Brochure contains highly confidential data and only people directly involved in the study should have access to the information.

6 Appendices

There are no appendices to this SOP.

7 Responsibilities

The Principal Investigator and all Sub-Investigators working on the study must be familiar with this SOP.

Before agreeing to act as an Investigator in a study all Investigators must have read and be familiar with the Investigator's Brochure.

8 Review

This SOP should be reviewed every two years unless new guidance or legislation dictates a review any sooner.

Date reviewed: 12/04/2019 Date of next review: 12/04/2021

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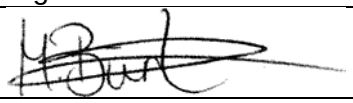
Written By	Signature	Date
Hazel Burt		12/04/19
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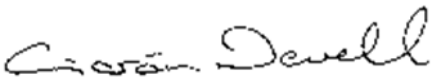
Dr Ciarán Newell		12/04/19
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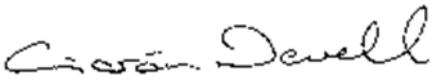
Dr Ciarán Newell		12/04/19