Research Governance Office Sponsorship

Standard Operating Procedures

Preparation and Management of the Investigator's Brochure (IB)

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Author	
Name	**Kyla Harrington**
Job Title	**Clinical Trials Governance Manager**
Reviewer/Approver	
Name	**Dr Cat Taylor**
Job Title	**Head of Research Governance**
Signature	
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1.0 Introduction and Scope

This Standard Operating Procedure (SOP) describes the process to be adopted by a Chief Investigator (CI) when producing an Investigator's Brochure (IB) for a trial involving an Investigational Medicinal Product (IMP) to be used in either a new indication or as a new compound. This SOP applies to all research studies (referred to as 'trials' hereafter) that are using IMPs and that are sponsored by the University of Leicester (UoL) where the UoL is required to prepare and maintain an IB. Where the preparation of the IB is delegated to a 3rd party (i.e., CTU, Service Provider) this must be detailed in the protocol and risk assessment. Where applicable, a contract must be in place, and the procedures of the 3rd party will be followed.

Where the IMP is supplied by a 3rd party (e.g., a pharmaceutical company), the Sponsor should determine whether an existing IB is available and suitable; if not, they must ensure one is created. In most cases, for UoL investigator-initiated trials, the IB will be authored and supplied by the marketing authorisation holder (MAH) but the UoL will remain responsible for ensuring that the IB is current, appropriate for the specific trial and indication, and it is reviewed/updated at least annually.

2.0 Definition

An IB is part of the clinical trial authorisation (CTA) application. It documents all relevant information about the IMP, including chemical structure, non-clinical trials and clinical trials.

It should be prepared from all available information and evidence that supports the rationale for the proposed trial and the safe use of the IMP within it. It should also detail which adverse reactions are expected and their frequency of occurrence, giving valuable safety information and guidance to the investigator(s) and Sponsor to use for assessing expectedness, and determining the expedited reporting requirements of any suspected unexpected serious adverse reactions (SUSARs).

3.0 When is a Full Investigator's Brochure Required?

- When conducting a CTIMP using a product that has not yet been granted a licensing authorisation (non- approved compound) a fully comprehensive IB is required.
- In cases where a licensed product is to be used outside of the licensed indication, or in a different subject population, it may be necessary to complete a full IB. However, it may be possible to use the existing Summary of Product Characteristics (SmPC) to support the use of the IMP in the trial.
- In cases where a licensed product is being used within the terms of its license an IB will not be required. The Reference Safety Information in the SmPC as published by the marketing authorisation holder will be an appropriate document to use.

4.0 4Preparation of the IB

The CI is responsible for co-ordinating the production of the IB. It is recommended that input from other relevant personnel (i.e., pharmacy or a specialist external

service provider) is sought, and that all review comments are retained. It is important that where comments have been submitted but not incorporated, a record is kept along with a brief explanation as to why the suggested changes were not made.

The IB forms part of the essential records for the trial, and must be included within the documentation submitted to the RGO to be reviewed as part of the Sponsor review process.

The IB template is provided in Appendix 1 and the IB must be prepared in accordance with published guidance (c.f., ICH GCP E6 (R3).

5.0 Review/Updates to the Investigator's Brochure

The IB must be reviewed on at least an annual basis and updated more frequently if significant new safety or efficacy data arise. The review and the decision to continue to use the existing version or to change the document must be documented using the UoL IB/SmPC review template (Appendix 2). This process must be completed irrespective of whether changes were necessary. It is expected that the relevant stakeholders be involved in the review/revision process of the IB.

More frequent review/revision may be appropriate, but this will depend on the stage of development of the drug or the generation of relevant new information. However, in accordance with GCP, relevant new information may be so important that it should be communicated to all Investigators, and possibly to the REC and/or regulatory authority before an IB revision has taken place.

A copy of the revised IB must be sent to the Sponsor for final sign off before it is submitted for regulatory approval. The IB requires signatures from the Chief Investigator, and the Sponsor for each version.

It is the responsibility of the CI to ensure that all sites have most recent approved version of the IB. It is expected that evidence be provided to show that the sites have received the latest version. An email trail will be acceptable evidence.

5.1 Submission of Revised Investigator's Brochures

Where an IB requires revision following review, modifications made to the document require regulatory approval. It is important to include the following information in the modification submission:

- how the risk/benefit assessment of the trial has been affected
- how these changes impact the trial
- what alterations to the protocol are proposed to take account of these changes?

6.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Version number	Description of changes
April 2026	4.0	• SOP = Language updates in accordance with ICH GCP E6(R3) and UK Clinical Trials Regulations. • Minor wording updates. • SOP cover page updated. • Removal of reference to SmPC because the UoL would not prepare or amend such a document. • Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive.