

	<b>Standard Operating Procedures</b>
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Procedure Category:	Document Management and Storage
Procedure CLN-05-03:	Investigator's Brochure

**Procedure Overview**

This procedure describes the necessary activities performed by MICHHR personnel in receiving, maintaining, and storing the Investigator's Brochure. If no Investigator Brochure, CLN-5-03 is not applicable.

**Responsible Individuals**

Investigator; Qualified MICHHR personnel (including, but not limited to, Study Coordinator and Research Assistant); Director, MICHHR

**Procedure**

The investigator and MICHHR personnel must maintain a copy of the Investigator's Brochure (IB) related to the specific study. If not Investigator Brochure, CLN-05-03 is not applicable. The IB should contain the following information:

- Title page
- Confidentiality Statement
- Table of Contents
- Summary
- Introduction
- Physical, Chemical, and Pharmaceutical Properties and Formulation
- Non-Clinical Studies
- Effects in Humans
- Summary of Data and Guidance for the Investigator
- References

The Investigator's Brochure is handled in the following manner:

1. As part of the investigator's / institution's written application to the Investigational Review Board (IRB), the investigator/MICHHR personnel provides a current copy of the IB. Refer to the IRBMED web page for additional details regarding submissions to the IRB.
2. The IB, a current copy of the protocol and IDS application are submitted for review by the Investigational Drug Service.
3. If the IB is updated/revised during the trial, the investigator/MICHHR personnel supply a copy of the updated/revised IB to the IRB and to the IDS.

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Approval Signature, Date:	

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4. MICHHR personnel files all revision/update replacement pages in the IB, according to sponsor/CRO instructions. The outdated pages and/or brochure(s) are NOT to be discarded, but must be retained for auditing purposes. Old documents are typically filed in reverse chronological order under an archive section of the IB or ISF. The frequency of revising or updating an IB varies depending on the amount and significance of new information.
5. MICHHR personnel ensure that the IB is maintained so that it is accessible only to staff listed on the FDA-1572 and the Signature Authorization Form. The sponsor/CRO may also have access.
6. MICHHR personnel distributes updated copies to study personnel as needed.
7. If an investigator is conducting more than one study with the same investigational product or several investigators at the same institution are conducting a study; only one IB may be maintained.

### Documentation

Documentation for this procedure includes all documentation relating to the IB including all versions of the IB.

### Deviation Approval

The Director, MICHHR or designee, must approve deviation from this procedure. The Director, MICHHR or designee, must store documentation of the deviation approval..

### Relevant Definitions

Investigator's Brochure (IB) - the IB is a comprehensive compilation of preclinical and clinical data about the investigational product, including its chemical and physical properties. It is a confidential document and is designed to serve as a reference for investigators

Initial IB - the IB prepared for and included in the Investigational New Drug Application (IND) that is submitted to the FDA.

Updated IB - contains important new information that requires issuing a revised IB. If enough new information is available to warrant notification of the investigators, the IB is updated.

Revised IB - includes replacement pages containing important new information or corrections. The IB is revised as needed when safety considerations arise or other important, but minimal data, need to be added quickly.

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**Procedure Author**  
Manager, Research Support Core

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