STANDARD OPERATING PROCEDURE **INVESTIGATOR BROCHURE VERSION CONTROL**	
SOP#: 6.2.6.3	**Original Approval Date: 12/5/14**
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1.0 PURPOSE/BACKGROUND

Study sponsors typically distribute updated Investigator Brochures to study staff members for those in which they are the IND holder. This Standard Operating Procedure (SOP) describes the process for obtaining updated versions of Investigator Brochures for all types of studies, including for National Clinical Trials Network (NCTN) studies where Cancer Therapy Evaluation Program (CTEP) or the Lead Protocol Organization (LPO) are the IND holders.

2.0 SCOPE

This SOP applies to all studies managed by the MCW Cancer Center Clinical Trials Office that involve an Investigator Brochure.

3.0 RESPONSIBILITY

Principal Investigators
Sub Investigators
Regulatory Staff
Other members of the study staff, as necessary

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions

CPR: Continuing Progress Report

CTEP: Cancer Therapy Evaluation Program

IND: Investigational New Drug

Investigator Brochure: a comprehensive document summarizing the body of information about an investigational product ("IP" or "study drug") obtained during a drug trial. It is of critical importance throughout the drug development process and is updated with new information as it becomes available.

NCTN: National Clinical Trials Network

NCI: National Cancer Institute

PMB: Pharmaceutical Management Branch

5.0 ROLES AND PROCEDURES

All Studies:

5.1 A notification of a new version of an Investigator Brochure received by any member of the study staff, should be forwarded to the regulatory staff for prompt submission to the IRB as required.

5.2 Investigator Brochures will not be submitted to the IRB of record as required once all study subjects are off study (no longer in follow up or deceased) and the study is permanently closed to accrual.

5.3 If an IB version was not submitted to the IRB in a timely manner because it was not received by the CCCTO regulatory staff from the sponsor at the time of release it will be submitted promptly to the IRB upon receipt, but will not be reported as a deviation.

NCTN Studies:

5.4 For NCTN studies where CTEP holds the IND, the regulatory staff must access current available versions of the IB on the Pharmaceutical Management Branch's website.

The current list of available versions of Investigator Brochures may be found on the NCI CTEP's Pharmaceutical Management Branch website: https://ctepcore.nci.nih.gov/aurora/login (Click "Online Agent Order Processing (OAOP) application".)

After logging in (CTEP login), the following information should be entered to obtain the most recent IB & summary of changes:

→ The investigator's name and NCI number (Investigator NCI numbers can be found on the "I" drive ("~Roster & NCI# Information" folder under "Regulatory".)

→ The name of the study agent (drug)

→ The protocol number (for example E1910)

5.5 It is the PMB's policy to only release the most recent version of the Investigator Brochure (past versions will not be released). If more than one version was released since the last inquiry, only the most recent version will be obtained and submitted to the IRB. A Note to File should be placed in the regulatory file explaining the missing version(s).

5.6 When a new version of an IB becomes available for NCTN studies for which the LPO holds the IND, the regulatory staff must follow the instructions on CTSU's website to initiate a document request to obtain the document.

6.0 REFERENCES

PMB FAQ: *How Do I Get an Investigator Brochure?*

21 CRF 312.55 *Investigational New Drug Application, Subpart D: Responsibilities of Sponsors and Investigators - Informing Investigators*

7.0 APPENDICES

None

Authorized by:	Signed Electronically by: Erin Lynch - eelynch@mcw.edu 21-Mar-2025 @ 01:16 PM CDT Reason: Approval CCCTO Administrative Director

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