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 various study staff members for studies in which they are the IND holder. For studies where CTEP is the IND holder, the PMB of the NCI distributes the updated Investigator Brochures to the study doctors whose NCI numbers were used to order study drug. Because of the variety of investigators involved and the volume of notifications that may be distributed, this SOP was developed to capture all versions of the Investigator Brochure for studies where the cooperative group is not the IND holder. This is also necessary as an Investigator Brochure may not be sent to participating sites if there is no enrollment to date. This Standard Operating Procedure (SOP) describes the process for obtaining updated versions of Investigator Brochures for which CTEP is the IND holder.

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.

NCI: National Cancer Institute

PMB: Pharmaceutical Management Branch

5.0 ROLES AND PROCEDURES

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.

5.2 Investigators are expected to forward to the regulatory staff any notifications received from the PMB regarding updated Investigator Brochures. If any other study staff members receive the notification from the PMB, they are also expected to forward the notification to the regulatory staff.

5.3 The regulatory staff will inquire with the PMB at the time of each amendment and each IRB annual renewal (CPR) whether a new version of the Investigator Brochure is available.

The current list of available versions of Investigator Brochures may be found on the NCI's Pharmaceutical Management Branch website: https://ctep.cancer.gov/branches/pmb/ib_list.htm (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)

5.4 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).

5.5 If an IB version was not submitted to the IRB according to the NCI 90-day policy because it was not received by the CCCTO regulatory staff from the NCI or Cooperative Group, it will be submitted promptly to the IRB, but will not be reported as a deviation.

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

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