

	Office of Sponsor and Regulatory Oversight	Document #: 408
	Determining When to Prepare an Investigator's Brochure Policy	Revision #: 1
		Effective Date: 18DEC2019

1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Determining When to Prepare an Investigator's Brochure (IB) when CCR is the manufacturer.

2. Scope

2.1. OSRO in the Center for Cancer Research (CCR), National Cancer Institute (NCI) shall establish and control the policy.

2.2. Investigators, research team members, other departmental personnel, and external NIH collaborators and contractors when they are working on studies conducted under a CCR-held Investigational New Drug (IND) application, or supported by a CCR-held Master File under OSRO oversight shall comply with the policy.

2.3. Limitations

2.3.1. Personnel are not bound to this policy when working on non-IND studies and/or no interdepartmental collaboration with OSRO as Sponsor is required.

2.3.2. Nothing in this policy will supersede NCI, National Institutes of Health (NIH) or Health and Human Services (HHS) requirements.

3. Responsibilities

3.1. The Center for Cancer Research Management is committed to providing resources to meet the requirements for implementing a Determining When to Prepare an Investigator's Brochure Policy within OSRO and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding and using the Determining When to Prepare an Investigator's Brochure Policy.

3.3. The OSRO Director is responsible for establishing and maintaining the Determining When to Prepare an Investigator's Brochure Policy.

4. References

4.1. ICH E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018

4.2. 21 CFR 312.55 – Investigational New Drug Application: Informing Investigators

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. OSRO will ensure that sufficient safety and efficacy data from nonclinical studies and/or clinical trials are available to support human exposure by the route, at the dosages, for the duration, and in the trial population to be studied.

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- 6.2. When CCR is the manufacturer, defined as when CCR is submitting the entire manufacturing information to the IND, the information can be included in the body of the protocol or in an IB.
- 6.3. OSRO Regulatory will determine when an IB is necessary according to the following guidelines:
 - 6.3.1. For the initial phase I study, conducted at the Clinical Center – the information will be included in the protocol, and no IB will be required.
 - 6.3.2. If the agent is used in more than two trials that include etiological distinct indications – an IB will be required.
 - 6.3.3. If the agent is used in a multicenter clinical trial – an IB will be required.
 - 6.3.4. When the agent is used in four or more clinical trials – an IB will be required.
- 6.4. The PI will provide any necessary information required for the IB that the manufacturer does not have.
- 6.5. OSRO will prepare an Investigator’s Brochure for investigational products manufactured in CCR facilities and by CCR personnel in accordance to ICH GCP E6 (R2) Section 7.0.
- 6.6. Once the threshold identified in Step 6.3 is reached, the IB should be prepared prior to initiation of further trials.
- 6.7. This policy shall be reviewed periodically and updated as necessary.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	18Dec2019	New Document