

	Office of Sponsor and Regulatory Oversight	Document #: 208
	Multicenter Clinical Trial Policy	Revision #: 1
		Effective Date: 22OCT2020

1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight’s (OSRO) Multicenter Clinical Trial Policy.

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, Investigational Device Exemption (IDE), 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 or IDE 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 Multicenter Clinical Trial Policy within OSRO and supporting its continual improvement.
- 3.2. OSRO personnel are responsible for understanding and using the Multicenter Clinical Trial Policy.
- 3.3. The OSRO Director is responsible for establishing and maintaining the Multicenter Clinical Trial Policy.

4. References

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

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

- 6.1. CCR will serve as the regulatory FDA IND/IDE Sponsor of a multicenter clinical trial only if:
 - 6.1.1. The CCR site Principal Investigator (PI) is also the Lead Investigator of the multicenter clinical trial and the NCI CCR site serves as the coordinating center for the trial, or

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- 6.1.2. The trial is run from a CCR established clinical trial network that serves as the coordinating center for the trial.
- 6.2. All non-NIH Clinical Center participating sites must sign the Sponsor-Site agreement to ensure CCR regulatory compliance and oversight.
- 6.3. CCR will only serve as the FDA IND/IDE Sponsor and will not serve as a Sponsor in any non-US areas. In case non-US sites are to be used:
 - 6.3.1. Prior approval by OSRO is required, and
 - 6.3.2. The non-US site will serve as the Sponsor in their local jurisdiction and will be in charge of local regulatory compliance.
- 6.4. The NIH NCI CCR coordinating center for the trial will be responsible for:
 - 6.4.1. Securing CCR leadership support for the multicenter trial;
 - 6.4.2. Selecting non-NIH sites;
 - 6.4.3. Negotiating the Sponsor-Site agreement for each participating site;
 - 6.4.4. Serving as the communication Point of Contact (POC);
 - 6.4.5. Oversight and reporting to the Sponsor for the operational and regulatory aspects for all the sites.
- 6.5. In case the CCR PI for a multicenter clinical trial leaves NCI:
 - 6.5.1. A new CCR PI will be assigned, or
 - 6.5.2. The IND will be transferred to the departing PI's new institution.
- 6.6. This policy shall be reviewed periodically and updated as necessary.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	22OCTO2020	New Document