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, non-NIH clinical site personnel, collaborators, and contractors when they are working on studies under a CCR-held IND, IDE, or an NSR device study or supported by a CCR-held Master File under OSRO oversight shall comply with the policy.

2.3. Limitations

2.3.1. This policy does not apply to personnel working on studies that are not under a CCR-held IND, IDE, or is an NSR device study, and/or when no OSRO oversight or interdepartmental collaboration 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. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO are responsible for understanding the Multicenter Clinical Trial policy.

3.4. The OSRO Director is responsible for establishing and maintaining the Multicenter Clinical Trial policy.

3.5. The multicenter protocol NCI CCR coordinating center is responsible for compliance with the Sponsor multicenter clinical trials policy and related procedures.

3.6. The clinical sites working on a multicenter protocol are responsible for compliance with the Sponsor multicenter clinical trials policy and related procedures.

4. References

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

4.2. 203 Clinical Trial Records Policy

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. CCR OSRO 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 Principal Investigator of the multicenter clinical trial, and the NCI CCR site serves as the multicenter protocol coordinating center for the trial, or

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 sites must sign a CCR clinical site agreement before the respective site may be initiated to ensure the non-NIH site's regulatory, clinical site monitoring, and safety reporting obligations are met.

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 multicenter protocol NCI CCR coordinating center will be responsible for the following:

6.4.1. Securing CCR leadership support for the multicenter trial;

6.4.2. Selecting non-NIH sites;

6.4.3. Negotiating the CCR clinical site agreement for each non-NIH site;

6.4.4. The development of the protocol-specific multicenter communication plan, including:

6.4.4.1. Completion and maintenance of the OSRO form F01-208-S01 Coordinating Center Communication Plan for Multi-Center Clinical Trials with version control and distribution of the initial and all updated versions to the Sponsor and non-NIH site(s).

6.4.4.2. Serving as the primary point of contact for non-NIH site communication with the Sponsor.

6.4.5. Ensuring the accuracy, quality and completeness of the non-NIH site clinical trial records per OSRO Policy 203, including:

6.4.5.1. Oversight of the site process for site clinical trial records development and maintenance, as warranted;

6.4.5.2. Review of records before submission to the Sponsor eTMF for review and acceptance by the OSRO SROS essential regulatory documents group;

6.4.5.3. Upload of documents to the Sponsor's eTMF

6.4.5.3.1. Before the first non-NIH site is initiated, the site personnel or the CCR coordinating center will be designated responsible for document upload and that designation will be specified in the CCR coordinating center communication plan.

6.4.5.3.2. The responsibility for document upload designation will apply over the duration of the study and across all sites without exception for all submissions.

6.4.6. Oversight of non-NIH sites, including:

6.4.6.1. As warranted, notify the Sponsor of issues or concerns with site performance;

6.4.6.2. Ensure site compliance with the CCR clinical site agreement;

6.4.6.3. Ensure site compliance with corrective and preventive action plans, as applicable;

6.4.6.4. Ensure site compliance with OSRO standard operational and regulatory requirements, including all clinical site monitoring activities, remote clinical data management system data entry and data cleaning requirements, and safety reporting;

6.4.6.5. Ensure the current communication plan is followed by the CCR coordinating center and the non-NIH sites.

6.5. In case the CCR Lead 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.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	22OCT2020	New Document
2	14NOV2022	Step 2.2 – added NSR Step 2.3.1 – updated Step 3.3 (SROS contractor) – added Section 4 – added hyperlink Step 6.6 – removed Updated document to meet current practices