

	Office of Sponsor and Regulatory Oversight	Document #: 206
	Clinical Site Activation Policy	Revision #: 2
		Effective Date: 05FEB2020

1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight (OSRO) Clinical Site Activation 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 and other departmental personnel and external NIH collaborators and contractors when they are working on studies conducted under a CCR-held Investigational New Drug application (IND), Investigational Device Exemption (IDE), or a National Institutes of Health (NIH) Institutional Review Board (IRB)-approved protocol using a Non-Significant Risk (NSR) device under OSRO oversight or supported by a CCR-held Master File under OSRO oversight shall follow the policy.
- 2.3. Limitations
 - 2.3.1. Personnel are not bound to this policy when working on non-IND, IDE or NSR studies and/or no interdepartmental collaboration with OSRO as Sponsor is required.
 - 2.3.2. Nothing in this policy will supersede NCI, NIH or Health and Human Services (HHS) requirements.

3. Responsibilities

- 3.1. CCR Management is committed to providing resources for implementation of the Clinical Site Activation policy and supporting its continual improvement.
- 3.2. OSRO personnel are responsible for understanding and using the Clinical Site Activation policy.
- 3.3. The OSRO Director is responsible for establishing and maintaining the Clinical Site Activation policy.
- 3.4. Investigators, research team members and other departmental personnel will start screening and enrollment of study participants only after the trial has been activated.

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.

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6. Policy

- 6.1. A clinical site will be activated to begin protocol-specific study participant screening and enrollment *only* after the following tasks have been completed:
 - 6.1.1. Site Initiation Visit (SIV) has been completed.
 - 6.1.2. All pertinent agreements have been fully executed.
 - 6.1.3. IND is safe to proceed; IDE or NSR has been approved, as applicable.
 - 6.1.4. Sponsor safety monitoring plan has been approved.
 - 6.1.5. Investigational Study Agent/Product(s)/materials are available on site and are ready to be dispensed, or manufacturing facility is ready for production for just in time manufactured products.
 - 6.1.5.1. Study agent will only be dispensed after Site Activation.
- 6.2. A Site Initiation Visit will be scheduled after:
 - 6.2.1. Site Assessment Visit (as warranted for non-NIH multicenter study participating sites with NIH coordinating center responsible for follow-up of any findings).
 - 6.2.2. Site essential documents (as identified in 203 Clinical Trial Records Policy – Table 1) are reviewed and accepted by OSRO.
 - 6.2.3. Clinical Monitoring Plan (CMP) has been finalized by OSRO.
- 6.3. The SIV Report generated after the visit shall indicate that there are no outstanding issues or action items identified. If issues are still outstanding, the Sponsor will confirm that all issues or action items identified at the SIV have been addressed adequately.
 - 6.3.1. Facilities that are required are available and acceptable.
 - 6.3.2. Study personnel have been trained on protocol and study procedures.
- 6.4. If the SIV was conducted more than 8 weeks before Site Activation, then protocol re-training by the study PI is required. Protocol re-training must be documented in the Site staff training records.
- 6.5. This Policy shall be reviewed periodically and updated as necessary.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	30Aug2019	New Document
2	05FEB2020	1. Added nonsignificant risk device to Section 2 Scope. 2. Added 203 Clinical Trial Records Policy to Section 4 References. 3. Revised the Site Initiation Visit prerequisites in Section 6 Policy.