1. **Purpose**

To describe the Sponsor’s clinical monitoring plan (CMP) development and maintenance based upon standard components and consideration of protocol, research team, facility and operational factors.

2. **Scope**

2.1. This SOP applies to clinical studies conducted under Center for Cancer Research (CCR) held Investigational New Drug applications (IND) or Investigational Device Exemptions (IDE) under Office of Sponsor and Regulatory Oversight (OSRO) oversight.

2.1.1. These intramural studies may be conducted at the National Institutes of Health (NIH) Clinical Center or at non-NIH institutions.

3. **Responsibilities**

3.1. OSRO Operations Coordinators oversee the process of developing and maintaining protocol-specific monitoring plans.

3.2. OSRO Clinical Site Monitors develop and maintain protocol-specific clinical monitoring plans.

4. **References**

4.1. 205 Clinical Site Monitoring Policy

5. **Definitions**

Refer to the OSRO Lexicon.

6. **Procedure**

6.1. Upon receipt of a protocol-specific Site Initiation Visit request, OSRO Operations will assign the new protocol to an OSRO Clinical Site Monitor.

6.2. The assigned Monitor will draft the CMP after reviewing the Institutional Review Board (IRB) approved protocol.

6.3. The OSRO Operations Coordinator will review and approve the protocol-specific CMP.

6.4. The approved CMP must be available before the start of monitoring activities.

6.5. CMPs will be evaluated by the OSRO Clinical Site Monitor and the OSRO Operations Coordinator for adequacy on a quarterly basis, at a minimum.

6.5.1. Unscheduled CMP reviews will be triggered by a change in the protocol, projected enrollment rate, facility or research team, or any significant non-compliance with regulations, Human Subjects Protection (HSP), Good Clinical Practice (GCP) or Sponsor requirements.

6.6. This SOP shall be reviewed periodically and updated as necessary.
7. Associated Documents

7.1. 205-S01-W01 Preparation and Review of Clinical Monitoring Plans

7.2. F01-205-S01 Clinical Monitoring Plan

8. Change Summary

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<th>Revision Number</th>
<th>Effective Date</th>
<th>Description of Change</th>
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<td>1</td>
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<td>New Document</td>
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