

	Office of Sponsor and Regulatory Oversight	Document #: 207
	<b>Continuity of Operations Policy</b>	Revision #: 1
		Effective Date: 28AUG2019

## 1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Continuity of Operations 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 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. Limitation

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 Continuity of Operations Policy within OSRO and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding and using the Continuity of Operations Policy.

3.3. The OSRO Director is responsible for establishing and maintaining the Continuity of Operations Policy.

## 4. References

Not applicable.

## 5. Definitions

Refer to the OSRO Lexicon.

## 6. Policy

6.1. During a disruption of operations, OSRO will maintain full operations as described in this policy.

6.2. OSRO staff who are eligible for telework are expected to continue their usual duty during a disruption of operations, from their telework location, except as detailed in 6.5.

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- 6.3. Less than 24-hour disruption
  - 6.3.1. Full operations will be maintained with activities conducted from remote telework locations.
- 6.4. Disruptions that are longer than 24 hours
  - 6.4.1. Full operations will be maintained with activities conducted from remote telework locations.
  - 6.4.2. If staff working from remote locations are unable to support full operations, then a reduction in operations may be implemented with prioritization of activities as follows:
    - 6.4.2.1. Assessment of Safety events.
    - 6.4.2.2. Reporting of SUSARs to the FDA.
    - 6.4.2.3. Reporting of time critical problems and time-sensitive responses to the FDA.
- 6.5. Lapse of Appropriations
  - 6.5.1. Only those staff members who are identified as excepted employees will be allowed to continue to perform duties from their duty station or remote location. All other staff are prohibited from working, or accessing any government furnished equipment or data system.
  - 6.5.2. The following activities will be prioritized:
    - 6.5.2.1. Assessment of Safety events.
    - 6.5.2.2. Reporting of SUSARs to the FDA.
    - 6.5.2.3. Reporting of time critical problems and time-sensitive responses to the FDA.
  - 6.5.3. Protocol activities:
    - 6.5.3.1. No new Site Activations will be issued, and no Site Initiation Visits will be performed.
    - 6.5.3.2. Ongoing protocols will not screen or enroll new study participants unless approved by the Clinical Center CEO.
    - 6.5.3.3. Participants who have enrolled and received a study mandated intervention (not necessarily the investigational agent) prior to the lapse of appropriation will continue on study according to the protocol.
  - 6.5.4. No other OSRO activities will be performed.
- 6.6. This policy shall be reviewed periodically and updated as necessary.

**7. Change Summary**

Revision Number	Effective Date	Description of Change
1	28AUG2019	New Document