	Office of Sponsor and Regulatory Oversight	Document #: 207
	Continuity of Operations Policy	Revision #: 3
		Effective Date: 24JUN2022

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 application (IND), Investigational Device Exemption (IDE), or Non-Significant Risk Device (NSR) 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, -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, 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. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO Functional Groups are responsible for understanding and using the Continuity of Operations Policy.
- 3.4. 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 and remote work are expected to continue their usual duty during a disruption of operations from their telework/remote location, except as detailed in Step 6.4.

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6.3. An individual employee who is teleworking or remote working and experiences a disruption to his/her home location operations should:

- 6.3.1. Immediately inform his/her supervisor about the disruption, and
- 6.3.2. Per the supervisor's instruction, the employee may be required to report to an NIH location, take leave, or be assigned work that does not require connectivity.

6.4. Lapse of Appropriations

- 6.4.1. Only those staff members who are identified as excepted employees will be allowed to continue to perform duties from their duty station or telework/remote location. All other staff are prohibited from working, or accessing any government furnished equipment or data system.
- 6.4.2. The following activities will be prioritized:
 - 6.4.2.1. Assessment of Safety events.
 - 6.4.2.2. Reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) to the Food and Drug Administration (FDA)
 - 6.4.2.3. Reporting of time critical problems and time-sensitive responses to the FDA.
- 6.4.3. Protocol activities:
 - 6.4.3.1. No new Site Activations will be issued, and no Site Initiation Visits will be performed.
 - 6.4.3.2. Ongoing protocols will not screen or enroll new study participants unless approved by the Clinical Center CEO.
 - 6.4.3.3. 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.
- 6.4.4. No other OSRO activities will be performed.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	28AUG2019	New Document
2	10JAN2022	Biennial review Step 2.2 – added Non-Significant Risk Device Study (NSR) Step 3.3 – added Updated document language as required
3	24JUN2022	Step 6.2 – added remote work locations Step 6.3 & 6.4 – removed Step 6.3 – added employee response to home operation disruption