	Office of Sponsor and Regulatory Oversight	Document #:	207
NATIONAL CANCER INSTITUTE — Center for Cancer Research	**Continuity of Operations Policy**	Revision #:	4
		Effective Date:	**27MAR2024**

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. 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 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

4.1. NIH Guidelines – Know Your Tier and Be Prepared, 08June2022

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. During a disruption of operations, OSRO will maintain 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
4	27MAR2024	Biennial Review Step 2.3.1 – clarified language Step 4.1 – added Step 6.1 – removed "full" from "full operations"