	Office of Sponsor and Regulatory Oversight	Document #: 411
	Emergency Exceptional Release of Product Policy	Revision #: 3
		Effective Date: 14JUN2024

## 1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight’s (OSRO) Emergency Exceptional Release of Product 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, other departmental personnel, and external NIH collaborators and contractors when they are participating in a CCR supported Nonsignificant Risk (NSR) Device Study or working on studies conducted under a CCR-held Investigational New Drug application (IND), Investigational Device Exemption (IDE), 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 an Emergency Exceptional Release of Product Policy within OSRO and supporting its continual improvement.
- 3.2. OSRO personnel are responsible for understanding and using the Emergency Exceptional Release of Product Policy.
- 3.3. The OSRO Director is responsible for establishing and maintaining the Emergency Exceptional Release of Product Policy.

## 4. References

- 4.1. [ICH E6\(R2\)](#) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018
- 4.2. [21 CFR §211.165](#) Current Good Manufacturing Practice for Finished Pharmaceuticals – Testing and release for distribution

## 5. Definitions

Refer to the OSRO Lexicon.

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## 6. Policy

- 6.1. As Sponsor, OSRO is responsible for ensuring that investigational products are manufactured in accordance with Good Manufacturing Practices.
- 6.1.1. Acceptance criteria provided in the regulatory submission for the sampling and testing conducted by the manufacturer’s quality control unit (or equivalent) shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release (21 CFR §211.165).
- 6.1.2. 21 CFR §211.165 also states that drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected.
- 6.2. In cases where an NIH manufactured product does not meet the regulatory established release criteria but is deemed vital to the patient in order to prevent imminent death or serious, irreversible injury, product release will follow the Sterile Product for Human Administration (SPHA) executive committee established processes. The SPHA will make the final determination whether the product can be released. The SPHA’s decision will override and serve as the Sponsor decision.

## 7. Change Summary

Revision Number	Effective Date	Description of Change
1	18MAR2020	New Document
2	04APR2022	Biennial Review Updated document language as required Step 2.2 – added NSR studies Step 2.3.1 – added NSR Section 4 – added hyperlinks Step 6.3 – removed
3	14JUN2024	Biennial Review Step 2.3.1 – clarified language