

	Office of Sponsor and Regulatory Oversight	Document #: 103
	Training Policy	Revision #: 3
		Effective Date: 05JAN2024

1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight (OSRO) training 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. Training for OSRO personnel is within scope.
- 2.3. Training for OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff who assist OSRO Functional Groups perform their duties is within scope.
- 2.4. Training for Investigators and those personnel performing clinical trial-related duties and functions for studies under a CCR-held Investigational New Drug application (IND), Investigational Device Exemption (IDE), Non-Significant Risk Device (NSR) for which OSRO serves as the Sponsor is within scope.
- 2.5. Limitations
 - 2.5.1. 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.
 - 2.5.2. Nothing in this policy will supersede NCI, National Institutes of Health (NIH) or Health and Human Services (HHS) requirements.

3. Responsibilities

- 3.1. CCR Management is committed to providing resources for a training program in compliance with the OSRO Quality Management System (QMS) requirements.
- 3.2. OSRO will establish Sponsor's requirements for site personnel training and training documentation.
- 3.3. OSRO personnel are responsible for understanding and using the QMS and its ancillary systems.
- 3.4. The OSRO Director is responsible for establishing and maintaining the OSRO QMS including personnel training component and/or ancillary learning management system.
- 3.5. CCR Management is responsible for permitting monitoring and auditing of personnel training records by OSRO and inspection by regulatory authorities, as appropriate.

4. References

- 4.1. [ICH E6\(R2\)](#) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018
- 4.2. [ICH Q10](#): Pharmaceutical Quality System, June 2008
- 4.3. ISO 9001:2008(E): Quality Management Systems – Requirements

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5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. OSRO Personnel Training

- 6.1.1. Personnel shall have the necessary education, background, training and experience to assure that all assigned responsibilities and activities are performed correctly.
- 6.1.2. A formal program for training personnel on OSRO procedures shall be established as part of each employee onboarding.
- 6.1.3. Records of training shall be maintained.

6.2. Sponsor and Regulatory Oversight Support (SROS) Contract Personnel Training

- 6.2.1. Personnel shall have the necessary education, background, training and experience to assure that all OSRO assigned responsibilities and activities are performed correctly.
- 6.2.2. Personnel shall train on OSRO policies.
- 6.2.3. Personnel shall train on OSRO procedures applicable to their assigned responsibilities.
- 6.2.4. Records of training should be maintained and be available for auditing by OSRO and inspection by regulatory authorities.

6.3. Site Personnel Training

- 6.3.1. Clinical personnel shall have the necessary education, background, training and experience to assure that all assigned trial-related duties and functions are performed correctly and comply with OSRO's Sponsor training requirements.
- 6.3.2. Records of training should be maintained and be available for monitoring and auditing by OSRO and inspection by regulatory authorities.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	02AUG2019	New Document
2	03JAN2022	Biennial review Step 2.3 – added Step 2.4 – updated Step 2.5.1 – updated Section 4 – provided hyperlinks for Steps 4.1 and 4.2 Section 6.2 – added Updated document language as needed
3	05JAN2024	Biennial review