

	Office of Sponsor and Regulatory Oversight	Document #: 103
	Training Policy	Revision #: 1
		Effective Date: 02AUG2019

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.
- 2.3. Training for Investigators and those personnel performing trial-related duties and functions for studies under a CCR-held Investigational New Drug (IND) application, Investigational Device Exemption (IDE), or Master File (MF).
- 2.4. Limitation
 - 2.4.1. Training for personnel working on non-IND or IDE studies is outside the scope of this policy.
 - 2.4.2. 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. U.S. Department of Health and Human Services' Guidance for Industry: E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), dated March 2018
- 4.2. International Conference on Harmonisation (ICH) Harmonised Tripartite Guideline: Q10: Pharmaceutical Quality System, dated June 2008
- 4.3. International Standard ISO 9001:2008(E): Quality Management Systems – Requirements, dated 2008

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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. Site Personnel Training

6.2.1. 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 the OSRO’s Sponsor training requirements.

6.2.2. Records of training should be maintained and be available for monitoring and auditing by OSRO and inspection by regulatory authorities.

6.3. This Policy shall be reviewed periodically and updated as necessary.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	02AUG2019	New Document