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

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