1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight's (OSRO) Qualified Medical Expertise 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. Clinical site medical personnel or consultants working on studies conducted under a CCR-held Investigational New Drug application (IND), Investigational Device Exemption (IDE), Non-Significant Risk Device or Master Files (MF) under OSRO oversight shall follow the policy.

2.3. Limitations

2.3.1. This policy does not apply to medical 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. CCR Management is committed to providing resources to meet the requirements for implementing the Qualified Medical Expertise Policy.

3.2. OSRO personnel are responsible for understanding the Qualified Medical Expertise policy.

3.3. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO are responsible for understanding the Qualified Medical Expertise policy.

3.4. The OSRO Director is responsible for establishing and maintaining the Qualified Medical Expertise policy.

4. References

4.1. ICH E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018

5. Definitions

Refer to the OSRO Lexicon.

6. Policy

6.1. Medical personnel will be qualified by education, training and experience before accepting responsibility for assigned clinical trial functions.

6.1.1. Evidence of qualifications will be by current curriculum vitae and/or other relevant documentation of licensure and training.

6.2. The Principal Investigator is responsible for ensuring the care and safety of study participants. The Principal Investigator may delegate this responsibility to other qualified, experienced and trained medical personnel.

6.3. SROS Contractor Medical Monitors will advise on trial-related medical questions or problems, serve as the Sponsor's assessor of a safety signal, and serve as reviewer and approver of relevant study-related documents.

7. Change Summary

Revision Number	Effective Date	Description of Change
1	05AUG2019	New Document
2	10JAN2022	Biennial Review Step 2.2 – added Non-Significant Risk Device Step 2.3.1 – changed to match other policy language Step 3.3 – added Step 4.1 – added hyperlink to reference Step 6.3 – added Updated document language as required
3	19MAR2024	Biennial review Step 2.3.1 – clarified language