	Office of Sponsor and Regulatory Oversight	Document #: 201
	Qualified Medical Expertise Policy	Revision #: 2
		Effective Date: 10JAN2022

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. Medical 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.
 - 2.3.2. 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.

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- 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